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## Datasheet for the decision of 20 May 2014

Case Number: T 2184/10 - 3.3.08

00936517.2 Application Number:

Publication Number: 1169463

IPC: C12N15/82, C12N15/40, C12N5/10,

A01H5/00

Language of the proceedings: ΕN

#### Title of invention:

METHOD FOR CONVEYING BNYVV RESISTANCE TO SUGAR BEET PLANTS

## Patent Proprietor:

Ses Europe N.V./S.A.

## Opponent:

Syngenta Crop Protection Ag.

## Headword:

Beet necrotic yellow vein virus resistance RNA1 replicase/SES

## Relevant legal provisions:

EPC Art. 84, 56, 112a(1), 113(1) RPBA Art. 12(4), 13(1) EPC R. 106

## Keyword:

Admissibility: Main Request and Auxiliary Request I (yes); Auxiliary Requests VI-VII (no) Main Request and Auxiliary Requests II-V - clarity (no) Auxiliary Request I - inventive step (no)

## Decisions cited:

G 0001/03, T 0423/01, T 0870/02, T 0005/08, T 2244/09

## Catchword:



## Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 2184/10 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 20 May 2014

Appellant: Ses Europe N.V./S.A.

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 27 August 2010 revoking European patent No. 1169463 pursuant to

Article 101(3)(b) EPC.

## Composition of the Board:

Chairman M. Wieser
Members: P. Julià
J. Geschwind

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## Summary of Facts and Submissions

- I. An opposition was filed against European patent 1 169
  463 on the grounds of Articles 100(a),(b) and (c) EPC.
  The opposition division considered the Main Request and
  Auxiliary Requests I to III (all filed on 9 June 2010
  at the oral proceedings before the opposition division)
  not to fulfil the requirements of Article 56 EPC.
  Auxiliary Request III was also considered to contravene
  Articles 123(2) and 84 EPC. Accordingly, the patent was
  revoked.
- II. An appeal was lodged by the patentee (appellant). With the statement of Grounds of Appeal, the appellant maintained the Main Request and Auxiliary Requests I to III filed in the first instance proceedings. It referred to three newly introduced documents.
- III. With letter of 19 May 2011, the opponent (respondent) requested the board to dismiss the appeal because none of the appellant's requests were considered to fulfil the requirements of Article 56 EPC. Auxiliary Requests I and II were also considered to contravene Articles 84 and 123(2) EPC, respectively. New documents D17 to D19 were filed to support the respondent's arguments. The respondent further requested that the three new documents referred to by the appellant were not admitted into the appeal proceedings as copies of these documents had not been provided.
- IV. On 11 May 2012, the appellant provided copies of the three documents cited in its Grounds of Appeal (which were designated as D20 to D22) and filed a new Main Request and Auxiliary Requests I to IV. According to the appellant, the Main Request and Auxiliary Requests I and III were identical to the Main Request and to the

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Auxiliary Requests I and II underlying the decision under appeal, respectively. Auxiliary Requests II and IV were new in the proceedings.

- V. On 17 December 2013, the board summoned the parties to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, the parties were informed of the board's preliminary opinion on some issues of the appeal case. In particular, the parties were informed that the board was of the opinion that all requests filed on 11 May 2012 were new in the proceedings and contained amendments that were not in line with the purpose of an appeal proceedings.
- VI. With letters of 18 and 17 of April 2014, the appellant and the respondent replied to the communication of the board, respectively. With its reply, the appellant filed a new Main Request and new Auxiliary Requests I to V.
- VII. Oral proceedings took place on 20 May 2014 in the presence of both parties. At these proceedings, the appellant filed a new document D23 and Auxiliary Requests VI and VII (infra).
- VIII. The **Main Request** was identical to Auxiliary Request I before the opposition division. Claims 1 and 19 read as follows:
  - "1. Method for conveying resistance to beet necrotic yellow vein virus (BNYVV) to a sugar beet plant, comprising the following steps:
  - (a) preparing a DNA fragment of at least 35 nucleotides in a sequence that is at least 70% homologous to the corresponding nucleotide sequence of

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the genomic RNA 1 of the beet necrotic yellow vein virus (BNYVV),

- (b) introducing said DNA fragment, operably linked to a promoter that is active in sugar beet plants, into a sugar beet plant cell to obtain a transformed sugar beet cell; and
- (c) regenerating a transgenic sugar beet plant from the transformed sugar beet plant cell; wherein said resistance is a durable resistance and in which the virus does not replicate."
- "19. Plant cell, exhibiting a resistance to BNYVV, comprising in its genome a DNA fragment of at least 35 nucleotides in a sequence which is at least 70% homologous to the corresponding nucleotide sequence of the genomic RNA 1 of said virus."
- Claims 2-9 were directed to preferred embodiments of claim 1. Claims 10-17 were directed to a DNA vector for conveying resistance to BNYVV to a plant, harboring a DNA fragment as defined in the methods of claims 1-8. Claim 18 was directed to a use of the vector of claims 10-17 for the transformation of a plant cell. Claims 20-27 were directed to preferred embodiments of claim 19. Claim 28 was directed to the use of a plant cell as claimed in claims 19-26. Claims 29-32 were directed to a BYNVV resistant sugar beet plant (claim 29), to BNYVV resistant progeny of said plant (claim 30), to seeds of said sugar beet plant and progeny (claim 31) and to vegetatively reproducible structures obtained from said plant and progeny (claim 32).
- IX. Auxiliary Request I was identical to the Main Request except for the deletion of claims 1-18. Claim 1 of Auxiliary Request I read as claim 19 of the Main Request.

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- X. Contrary to Auxiliary Request I, Auxiliary Requests II

  to V contained claims directed to a method for
  conveying resistance to BNYVV. In all these requests,
  the claimed method comprised, inter alia, the feature
  "wherein said resistance is a durable resistance and in
  which the virus does not replicate".
- XI. Auxiliary Request VI was essentially identical to Auxiliary Request I except for the fact that claim 1 required a degree of homology of 90% instead of 70%. Claim 1 of Auxiliary Request VII read as follows:
  - "1. Plant cell, exhibiting a resistance to BNYVV, comprising in its genome a DNA fragment identical to nucleotides 153 to 3258 of the corresponding nucleotide sequence of the genomic RNA 1 of said virus."
- XII. The following documents are referred to in this decision:
  - D1: WO-A1-98/07875 (publication date: 26 February 1998);
  - D6: J.P. Carr and M. Zaitlin, Seminars in Virology, Vol. 4, 1993, pages 339 to 347;
  - D7: R. Koenig, Nachrichtenbl. Deut. Pflanzenschutzd., Vol. 40, No. 6/7, 1988, pages 88 to 92;
  - D8: S. Bouzoubaa et al., J. Gen. Virol., Vol. 68, 1987, pages 615 to 626;
  - D9: W.G. Dougherty and T. Dawn Parks, Current Opinion in Cell Biology, Vol. 7, 1995, pages 399 to 405;

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D19: R. Johnson, Ann. Rev. Phytopathol., Vol. 22, 1984, pages 309 to 330;

D23: Q. Ge et al., RNA, Vol. 16, 2010, pages 106 to 117:

WO-A1-00/68374 (publication date: 16 November 2000; cited in appellant's Grounds of Appeal by referring to corresponding EP 1801215).

XIII. Appellant's submissions, insofar as they are relevant to the present decision, may be summarized as follows:

## Admissibility of the Main Request and of Auxiliary Request I

These requests were filed in direct reply to the communication of the board pursuant to Article 15(1) RPBA and to the observations made therein regarding the non-admissibility of former requests. The Main Request was identical to Auxiliary Request I before the opposition division which, in the decision under appeal, was considered to fulfil all requirements of the EPC except for Article 56 EPC. Auxiliary Request I was identical to the Main Request except for the deletion of the method claims. This deletion simplified the subject-matter of the appeal and was made in direct reply to the board's observations regarding the mechanism of action of these methods.

## Main Request

Article 84 EPC; admissibility of document D19

The term "durable resistance" was a conventional term in the field of the invention and was not ambiguous. A "durable resistance" could be measured by conventional

assays known to a skilled person. The term required the resistance to be present over the whole life of the plant (as acknowledged in the decision under appeal), to be stably transmitted to the plant progeny and to be effective over different strains of the virus and in different soils. The definition of the term "durable resistance" given in the decision under appeal did not exclude the presence of other properties, such as the presence of a stable transmission of said resistance to the plant progeny. Indeed, it was well-known that, for transgenic plants, a method which did not result in the resistance being stably transmitted to the progeny was technically irrelevant and meaningless.

Document D19 was late filed and was concerned with conventional plants only, not with transgenic plants. Its content did not contradict the definition of the term "durable resistance" given in the decision under appeal. Therefore, it should not be admitted into the appeal proceedings.

# Auxiliary Request I Article 56 EPC The closest prior art

Prior art documents disclosing the production of transgenic sugar beet plants by using a DNA fragment encoding the coat protein (CP) of the beet necrotic yellow vein virus (BNYVV) were on file. The resulting transgenic plants showed a limited BNYVV resistance, i.e. a reduced or lower BNYVV infection, but none of these transgenic plants showed complete BNYVV resistance, all attempts to achieve such a resistance had not been successful. Document D1, which represented the closest prior art, disclosed experiments in which sugar beet plants were inoculated inter alia with

several BNYVV RNA2 constructs. These experiments showed that an over-expression of the p15 protein (encoded by the RNA2 triple gene block 3, TGB3) over the p13 protein (encoded by TGB2) induced BNYVV resistance. Document D1 further disclosed the production of transgenic sugar beet plants comprising a TGB3 DNA fragment encoding the p15 protein and reported the results of said transformation. However, there was no result showing the actual BNYVV resistance of these transgenic sugar beet plants. In absence of this information, the presence of a BNYVV resistance, let alone a complete BNYVV resistance, in these transgenic sugar beet plants was only hypothetical, not confirmed by any technical evidence.

## Objective technical problem

Starting from document D1, the technical problem to be solved, was the provision of a transgenic sugar beet plant with an actual, i.e. demonstrated by technical evidence, complete BNYVV resistance. The provision of such a transgenic sugar beet plant was an improvement over the prior art and not a mere alternative thereto, since a transgenic sugar beet plant with a complete BNYVV resistance had never been disclosed in the prior art.

Solution proposed by the patent; admissibility of document D23

Example 3 of the patent showed that transgenic sugar beet plants with a DNA fragment of the genomic RNA1 of BNYVV had a complete BNYVV resistance under high BNYVV pressure and thus, solved the technical problem. The post-published document WO 00/68374 showed that other DNA fragments of the genomic RNA1 of BNYVV (with

shorter sequence length) also provided a complete BNYVV resistance. Short DNA fragments (22 nucleotides) were also known from the prior art to be effective in RNA silencing. The claimed subject-matter was in line with the disclosure in this prior art, which was common general knowledge of a skilled person. There was no reasoning, let alone any evidence on file, casting serious doubts on the fact that the technical problem was solved over the entire scope of the claims.

Products (DNA fragments of RNA1 BNYVV), assays and methods (ELISA, Southern blot, etc.) for carrying out the invention were disclosed in the patent, as shown in Example 3. A skilled person would not have faced any technical problems to identify and select transgenic sugar beet plants having the desired properties and to disregard transgenic plants without them. According to established law, it was not required to disclose the actual mechanism of action but only to provide the technical means necessary to put an invention into practice. In the post-published document WO 00/68374, the technical effect disclosed in the patent (complete BNYVV resistance) was also obtained and the actual mechanism of action was not identified. This mechanism was identified only later in documents such as post-published document D23, which was submitted in direct reply to the board's observations in this respect.

Obviousness and expectation of success

Document D1 did not suggest the selection of a DNA fragment of the genomic RNA1 of BNYVV. On the contrary, many other targets and alternatives were disclosed in this document such as, for instance, to complete the studies on the effect of the genomic RNA2 TGB3.

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Although BNYVV was known to have a small genome, hindsight was necessary for selecting the genomic RNA1 of BNYVV. The more so since document D1 showed that not each (over-expression of) RNA2 TGB genes had the desired resistance effect. Significant results were obtained in document D1 only with inoculated sugar beet plants. There was no information regarding transgenic sugar beet plants required a further technical step that was not obvious in the light of the multiple and complex inoculation studies disclosed in document D1.

In the absence of any suggestion in the prior art, hindsight was required to combine the disclosures of documents D1 and D6. Although document D6 referred to a long list of plants and plant viruses, there was no reference to BNYVV and/or to sugar beet plants.

Moreover, the results reported in document D6 were contradictory and not conclusive. Whereas some resistant transgenic plants were obtained by using DNA fragments encoding viral replicases, other transgenic plants showed no resistance at all when transformed with similar DNA fragments. In view of these results, a skilled person could not have had any expectation of success.

Document D7, a review article, referred to BNYVV and sugar beet plants in general. The experiments with BNYVV mentioned in this document were unpublished and not disclosed in sufficient detail. Although studies on defective BNYVV RNAs in roots of sugar beet plants were referred to, there was no information as regards to which RNA was defective and which deficiency was actually present. Document D7 further referred to several known problems for producing transgenic sugar beet plants. In summary, this document put forward

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several questions but did not provide any technical evidence or data answering them. Its disclosure was only speculative and thus irrelevant.

## Admissibility of Auxiliary Request VI

The request overcame an objection based on document D9, which had been raised by the board for the first time at the oral proceedings. The feature introduced into this request (90% homology) took into account the relevant disclosure of document D9. Although the board referred to other "specific DNA fragments" in its communication pursuant to Article 15(1) RPBA, this term was not further elaborated and, in this context, was understood to refer to the specificity of the target sequence within the BNYVV RNA1 but not to be of relevance for the issue of homology. Earlier in the proceedings, evidence had been filed to show that the effect disclosed in the patent was also achieved by DNA fragments of BNYVV RNA1 with a length and sequence different from those used in the patent. The burden of proof, to show that its allegations regarding DNA fragments with sequences of low homology were indeed correct, lied on the respondent.

## <u>Violation of the right to be heard (Objection under Rule 106 EPC)</u>

At the oral proceedings, the appellant was taken aback by the board's reference to document D9 and the objection regarding the low degree of homology of the DNA fragment used in claim 1. The appellant was not given an opportunity to overcome this objection by filing an auxiliary request that took into account this unexpected objection since Auxiliary Request VI was not admitted into the appeal proceedings. Thereby, the

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appellant's right to be heard was violated (Article 113(1) EPC).

## Admissibility of Auxiliary Request VII

The claims of this request were limited to the BNYVV RNA1 sequence used in Example 3 of the patent. The filing of this request was a direct reply, both to the objections raised for the first time at the oral proceedings in appeal, in particular those based on document D9 regarding the low degree of homology of the DNA fragment used in claim 1, and to the board's unexpected conclusions on other requests of the appellant. The appellant could not be deprived of its right to defend its case when it had been surprised by new objections. Auxiliary Request VII, prima facie, overcame all objections discussed at the oral proceedings and which had been raised during the entire opposition and appeal proceedings.

XIV. Respondent's submissions, insofar as they are relevant to the present decision, may be summarized as follows:

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In reply to the respondent's observations to the statement of Grounds of Appeal, the appellant had withdrawn all requests underlying the decision under appeal. The reintroduction of one of these requests (Auxiliary Request I in opposition) at a later stage of the appeal was an amendment to the appellant's case that, prima facie, did not overcome the objections raised at earlier stages of the proceedings and that, in view of the large number of requests filed and

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withdrawn during the whole proceedings, was unfair to the respondent.

## Main Request

Article 84 EPC; admissibility of document D19

There was no definition of the term "durable resistance" in the patent. Indeed, several terms were used therein, such as total, absolute and complete resistance, but no definition was provided for any of them. All these terms were also used in the appellant's Grounds of Appeal without further definition. The term "durable resistance" was open to interpretation, as shown by the meaning given to this term in the decision under appeal (resistance during essentially the whole plant's life), in the appellant's reply to the board's communication (resistance evidenced by plant's progeny, i.e. stable inherited genome insertion) and in document D19 (with reference to viral infection time, area and degree of exposure, etc.). This lack of clarity rendered the claimed subject-matter ambiguous.

The interpretation of the term "durable resistance" became relevant only upon the filing of Auxiliary Request I at the oral proceedings before the opposition division and in the light of the interpretation of this term in the decision under appeal. Document D19 was filed in reply to this decision and thus, at the earliest time possible.

# Auxiliary Request I Article 56 EPC

The closest prior art

Document D1, the closest prior art, disclosed the production of transgenic sugar beet plants using a

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specific DNA fragment of the genomic RNA2 (TGB3) of BNYVV. Based on the results of inoculation studies, BNYVV resistant transgenic sugar beet plants comprising said DNA fragment, or fragments with 70% homology thereto, were claimed in document D1. There was no evidence in document D1 demonstrating the BNYVV resistance, however, the same applied to the patent, which also did not demonstrate the claimed BNYVV resistance for all embodiments falling within the scope of the claims.

## Objective technical problem

Starting from document D1, the technical problem to be solved was the provision of an alternative transgenic sugar beet plant with BNYVV resistance.

Solution proposed by the patent; admissibility of document D23

The DNA fragment used in Example 3 of the patent had a length of more than 3000 nucleotides, the one used in the post-published document WO 00/68374 of more 1000 nucleotides. In Example 3, no BNYVV resistance was obtained for transgenic plants having a single insertion (one band on Southern blot). Moreover, there was no evidence on file to show that BNYVV resistance could be obtained with DNA fragments of a short length (35 nucleotides) and low (70%) degree of homology.

The mechanisms of action underlying the invention had been already discussed at earlier stages of the proceedings. Document D23 was late filed and not relevant. In the patent and in post-published document WO 00/68374, very specific DNA fragments were used,

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whereas the disclosure of document D23 was of a general character and had no bearing on sugar beet plants.

Obviousness and expectation of success

BNYVV was known to have a small genome (inter alia from document D8) and thus, only few possible alternative target genes were available to a skilled person. No hindsight was required to acknowledge this fact. Document D1 referred to known studies in which the BNYVV coat protein (CP) was used for producing BNYVV resistant transgenic sugar beet plants and BNYVV RNA1 and RNA2 were identified as essential genes. Since document D1 was concerned with BNYVV RNA2, it was obvious to select the other essential BNYVV RNA1 gene, known to comprise a replicase gene, for further studies. The more so, since document D6 reported the successful use of viral replicase genes for producing resistant transgenic plants. Although a few negative results were reported in document D6, there was no reason for a skilled person to disregard the incentive provided by this document and not to contemplate the use of the replicase gene within the BNYVV RNA1 gene for the same purpose. Thus, the combination of documents D1 and D6 was obvious and the disclosure of document D6 provided a reasonable expectation of success.

## Admissibility of Auxiliary Request VI

Document D9 was filed with the Notice of opposition and its content was already discussed at the beginning of the opposition proceedings in the same context and for the same reasons as those put forward at the oral proceedings in the appeal procedure. Auxiliary Request VI was late filed and no reasons were provided to

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explain why it could not have been filed earlier in the proceedings. Moreover, the request did not, prima facie, overcome all the objections on file.

## Admissibility of Auxiliary Request VII

The issues, arguments and objections discussed at the oral proceedings in the appeal procedure had already been on the table since the beginning of the opposition proceedings and during the appeal proceedings, as shown, inter alia, by the references in the Notice of opposition to document D9 and to the relevance of the degree of homology. No reasons were provided to explain why the request could not have been filed at earlier stages of the proceedings. The filing of this request at the very end of the oral proceedings in the appeal proceedings, when the board had already announced its conclusions with regard to all other requests of the appellant, was too late and came close to an abuse of procedure.

- 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 of Auxiliary Requests I to V all filed with letter of 18 April 2014 (under consideration of corrections to be made in the back reference in claim 12 of the Main Request and of Auxiliary Requests II and III), or on the basis of Auxiliary Requests VI or VII, both filed at the oral proceedings before the board.
- XVI. The respondent (opponent) requested that the appeal be dismissed.

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## Reasons for the Decision

## Admissibility of the Main Request and of Auxiliary Request I

- I filed at the oral proceedings before the opposition division. This request was maintained with appellant's Grounds of Appeal and later withdrawn in reply to the comments made by the respondent to these Grounds of Appeal. The request was reintroduced into the appeal proceedings in reply to the board's communication pursuant to Article 15(1) RPBA and in preparation of the oral proceedings before the board (cf. points II, IV and VI supra).
- 2. The board sees no reason for not admitting the Main Request into the appeal proceedings. The reintroduction of this request into the appeal proceedings does not increase the complexity of the subject-matter under consideration. Indeed, the essential subject-matter of the Main Request was always present in the appeal proceedings since it was present in some of the appellant's requests filed in reply to the comments made by the respondent to the appellant's Grounds of Appeal and considered by the board in its communication pursuant to Article 15(1) RPBA (cf. points IV and V supra).
- 3. Auxiliary Request I is identical to the Main Request except for the deletion of the method claims 1-18 of the Main Request (cf. points VIII and IX supra). The amendments introduced into Auxiliary Request I overcome an objection of lack of clarity that was addressed and decided in the appellant's favour in the opposition proceedings (cf. page 12, point 4.1.1 of the decision under appeal). All claims of Auxiliary Request I are

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present in the Main Request and thus, the board, as for the Main Request, sees no reason for not admitting this request into the appeal proceedings.

4. The board, in exercise of its discretion, decides to admit the Main Request and Auxiliary Request I into the appeal proceedings (Article 13(1) RPBA).

## Main Request

Article 84 EPC; admissibility of document D19

- 5. In comparison to claim 1 as granted, the Main Request requires the DNA fragment used in step (a) of claim 1 to be "of at least 35 nucleotides" (instead of 15 nucleotides) and the conveyed BNYVV resistance to be "a durable resistance and in which the virus does not replicate" (cf. point VIII supra). The term "durable resistance" was objected under Article 84 EPC for lack of clarity in the opposition proceedings and the opposition division decided that the term fulfilled the requirements of this article (cf. page 12, point 4.1.1 of the decision under appeal).
- 6. In reply to the appellant's Grounds of Appeal, the respondent maintained the objection of lack of clarity for the term "durable resistance" and filed document D19 to support its arguments (cf. point III supra). Document D19 is a general review which is, as its title indicates: "A critical analysis of durable resistance", clearly concerned with the objected term. Since the feature in claim 1 comprising the objected term was introduced for the first time with the filing of an auxiliary request at the oral proceedings before the opposition division, the board agrees with the respondent that there was no opportunity to file

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document D19 at an earlier stage of the proceedings (cf. point XIV *supra*).

- 7. Thus, the board, in exercise of its discretion, decides to admit document D19 into the appeal proceedings (Article 12(4) RPBA).
- 8. As for the objection under Article 84 EPC for lack of clarity of the term "durable resistance", the board notes the following:
- 8.1 As argued by the respondent (cf. point XIV supra), there is no definition for this term in the patent. In fact, several terms are used in the patent, such as "total resistance" and "absolute resistance" (cf. page 2, paragraph [0011], line 56, page 4, paragraph [0028], lines 44, 49 and 50, page 7, paragraph [0048], line 3 of the patent). However, the patent does not define the precise meaning of each of these terms. In the decision under appeal, the opposition division considered the term "durable resistance" to be clear to a skilled person and it further defined this term as meaning a "resistance during essentially the whole life of a plant" without specifying any other limitation and/or requirement (cf. page 12, point 4.1.1 of the decision under appeal).
- This definition closely resembles the definition of this term given in document D19, namely "a resistance that remains effective during its prolonged and widespread use in an environment favorable to the disease" (cf. page 309, first paragraph of document D19). However, document D19 refers to several elements for measuring and/or testing a "durable resistance", including time (long), area (large), number of pathogen races or subtypes, disease pressure, etc. and it

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further differentiates between the effectiveness or level of resistance and its durability. Indeed, it is explicitly stated that "(t)here is clearly a subjective element in the decision to describe the resistance of a cultivar as durable", further adding that "(i)n many instances the decision will depend partly on the relative performance of other cultivars" (emphasis added by the board) (cf. page 310, third paragraph of document D19).

- 8.3 The appellant, in its reply to the board's communication pursuant to Article 15(1) RPBA, argued that a "demonstrated durable resistance against BNYVV" is "evidenced by its progeny (i.e. with stable inherited genome insertion)" (cf. inter alia, page 10, fourth paragraph, page 15, last but one paragraph of the appellant's letter dated 18 April 2014; point VI supra). This is also evident from the subject-matter exemplified in the patent, where the bioassay for BNYVV resistance was carried out using the transgenic F1 seeds (cf. page 6, Examples 2 and 3 of the patent). Although, as stated by the appellant (cf. point XIII supra), the definition of the term "durable resistance" given in document D19 and by the opposition division in the decision under appeal did not exclude this further requirement, it did not necessarily include it.
- 9. In the light of the factual situation described above and under specific consideration of the arguments presented by the appellant itself, the board concludes that the term "durable resistance" has no generally accepted meaning in the here relevant technical field and is thus open to interpretation. As such it is ambiguous and renders the scope of claim 1 unclear. Thus, the Main Request does not fulfil the requirements of Article 84 EPC.

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## Auxiliary Request I

Article 123, 84 and 54 EPC

- 10. No objections were raised by the respondent under any of these articles and the board sees no reason to raise any of its own. According to the decision under appeal, no objections were raised under Article 54 EPC with regard to the subject-matter of the Main Request or of Auxiliary Requests 1-3 before the opposition division, which is essentially identical to the subject-matter of Auxiliary Request I in appeal proceedings (cf. points VIII to IX and 1 to 4 supra).
- 11. Thus, the board considers Auxiliary Request I to fulfil the requirements of Articles 123, 84 and 54 EPC.

#### Article 56 EPC

12. With regard to non-achieved technical effects, decision G 1/03 of the Enlarged Board of Appeal (OJ EPO, 2004, page 413, point 2.5.2 of the Reasons) indicates the following: "...(i)f an effect is expressed in a claim, there is lack of sufficient disclosure. Otherwise, i.e. if the effect is not expressed in a claim but is part of the problem to be solved, there is a problem of inventive step ...".

Claim 1 of Auxiliary Request I requires the claimed plant cell to exhibit a BNYVV resistance. Thus, although a certain technical effect is explicitly expressed in the claim, there is no further requirement attached to said BNYVV resistance. In particular, claim 1 does not require an absolute, complete or total BNYVV resistance, let alone "a durable resistance" as claim 1 of the Main Request, which according to the appellant

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is to be understood as a stable inherited BNYVV resistance (cf. point 8 supra). The achievement of such specific technical effect, which is not expressed in the claim but forms part of the problem to be solved (cf. point 15 infra), is an issue that has to be assessed under Article 56 EPC.

13. The board observes that also the decision under appeal (besides Article 100(c) EPC) is exclusively concerned with the issue of inventive concept. Therefore, although the respondent has also raised an objection under Article 83 EPC, the board considers it to be appropriate to immediately turn to the examination of Auxiliary Request I in the light of the requirements of Article 56 EPC.

## The closest prior art

- 14. Document D1, representing the closest prior art, discloses several (replicon) constructs with several different combinations of the genes within the triple gene block (TGB) comprised in the sense-plus BNYVV RNA2, namely the viral proteins P42 (TGB1), P13 (TGB2) and P15 (TGB3). Combinations of these constructs are used to infect Chenopodium quinoa protoplasts and to co-inoculate (with wild-type BNYVV RNA1 and with, or without, BNYVV RNA3) quinoa and Beta macrocarpa leaves and roots (cf. page 13, line 28 to page 17, line 8 and Figure 1 of document D1).
- 14.1 Based on the results from these infection studies, it is concluded that the "expression of P15 in transgenic plants could provide a mechanism for inducing BNYVV-resistance ("pathogen-derived resistance"; ...) in such plants, provided that sufficient P15 expression levels can be attained" (cf. page 28, line 29 to page 29, line

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- 1 of document D1). Accordingly, transgenic (Beta vulgaris) sugar beet plants having a BNYVV TGB3 gene encoding the BNYVV P15 protein integrated into their genome are also provided (cf. page 29, line 28 to page 37, line 6, Figures 7 and 8 of document D1).
- Although document D1 contains no results indeed showing the BNYVV resistance of the transgenic sugar beet plants, it explicitly claims a method for inducing resistance to a virus (such as BNYVV) comprising the transformation of a plant cell (preferably from a sugar beet) by a nucleic acid construct comprising a nucleic acid sequence corresponding to at least 70% of the nucleic acid sequence of TGB3 of said virus (preferably at least 90%), or the specific TGB3 nucleic acid sequence and the regeneration of a transgenic plant from the transformed plant cell. Transgenic sugar beet plants resistant to BNYVV virus are also referred to and explicitly claimed in document D1 (cf. page 9, lines 17 to page 13, line 1 and claims).
- 14.3 According to the established case law, the same standard has to be applied when assessing the disclosure of a prior art document and that of the patent specification (cf. inter alia, decisions T 870/02 of 16 September 2004, point 6 of the Reasons; T 423/01 of 25 March 2004, point 21 of the Reasons; T 2244/09 of 11 June 2013, point 8.3 of the Reasons). Although the teaching of the patent is exemplified by a specific embodiment of the alleged invention (cf. point 17.1 infra), there are no experimental data in the patent to exemplify other embodiments (cf. point 17.2 infra). The appellant has referred to the prior art and to the common general knowledge of a skilled person in the field for supporting these non-exemplified embodiments (cf. point XIII supra). It is the same

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prior art and the same common general knowledge which has to be used for assessing the disclosure of document D1 and which, in the board's view, supports indeed the disclosure of this document.

## Objective technical problem

15. Starting from document D1, the objective technical problem is, as also formulated by the appellant (cf. point XIII *supra*), the actual provision of a transgenic sugar beet plant with a complete BNYVV resistance.

Solution proposed by the patent; admissibility of document D23

- 16. According to the problem-solution approach established by the Boards of Appeal, once the objective technical problem is formulated, it is then necessary to assess whether the solution proposed by the patent and, more particularly the claimed subject-matter, solves this technical problem and, indeed, whether the problem is solved over the whole scope of the claim. In the present case, the proposed solution is a plant cell comprising in its genome a DNA fragment of the BNYVV RNA1 sequence, wherein said sequence is further defined by its length (at least 35 nucleotides) and degree of homology (at least 70%) to the corresponding sequence of the genomic BNYVV RNA1 (cf. points VIII and IX supra).
- 17. It is relevant to note that claim 1 does not expressly require the presence of a complete BNYVV resistance but merely refers to "a resistance to BNYVV" (cf. point 12 supra). Claim 1 covers cells comprising a DNA fragment of at least 35 nucleotides, thus comprising long as well as short DNA fragments.

17.1 As for DNA fragments with long nucleic acid sequences, the examples of the patent show that the transformation by a DNA fragment having a nucleic acid sequence longer than 3000 nucleotides (identical to nucleotides 153-3258 of BNYVV RNA1; cf. page 5, paragraph [0039] of the patent) results in totally (completely) BNYVV resistant transgenic sugar beet plants (T157-01 derived F1 progeny; cf. pages 6-7, Examples 2-3 of the patent). However, said complete BNYVV resistance is exhibited, only and exclusively, by transgenic sugar beet plants having two or three DNA fragments integrated into their genomes (2 or 3 bands on the Southern blot); all transgenic plants with a single DNA fragment (single band on Souther blot) are susceptible to BNYVV infection (cf. page 7, paragraph [0049] of the patent).

In this context the appellant has referred to post-published document WO 00/68374 (cf. point XIII supra). Example 9 of this document shows that the transformation by a BNYVV RNA1 fragment with a nucleic acid sequence longer than 1000 nucleotides (cf. page 34, Example 9.1) results in BNYVV resistant transgenic sugar beet plants (cf. pages 36-38, Examples 9.2-9.3 of WO 00/68374). However, the BNYVV fragment used has a very particular structure (sense and antisense, duplex RNA fragment) and the document does not contain a detailed characterization of the BNYVV resistant clones resulting from the disclosed transformation events.

In view of the evidence on file, the board is not convinced that the technical problem formulated above is indeed solved by a subgroup of products falling within the scope of claim 1, namely transgenic plant cells comprising in their genome, only and exclusively, a single DNA fragment of the BNYVV RNA1 of a length as defined in document D1 and in WO 00/68374.

As for DNA fragments with short nucleic acid sequences, there is no example in the patent showing a BNYVV resistance in transgenic sugar beet plants transformed by such a DNA fragment. Instead the appellant refers to the prior art and to the common general knowledge of a skilled person in the field of the sense/antisense RNA inhibition. Indeed, in the decision under appeal, the opposition division considered that it is "... commonly accepted teaching in the state of the art that the successful inhibition by nucleic acids requires fragments of at least 20 or 21 nucleotides with almost 100% identity ..." (cf. page 9, point 3.2.3 of the decision under appeal).

However, the opposition division did not acknowledge this "accepted teaching" to extend to nucleic acids of 15 nucleotides with only a 70% identity to BNYVV RNA1. In this context, a reference of the proprietor/appellant to document D9 ("... studies with these short oligonucleotides (often 10-40 nucleotides [nt] long) indicate that these compounds are able to act transiently ..."; cf. page 399, right-hand column, last paragraph of document D9) was found not to be sufficient to convince the opposition division, since "(a) it refers to transient activity, i.e. not to durable, continuous activity and (b) it does not address the issue of oligonucleotides being only 70% identical to the target sequence" (cf. page 9, point 3.2.3 of the decision under appeal).

The board further notes that document D9 explicitly refers to the fact that "(t) ransgenic plant virus resistance studies have shown that the transgenederived transcript and the viral genome are specifically eliminated from the cell when they show

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>90% homology. However, a virus sharing 65-70% homology is not recognized and replicates normally ...

Therefore, there is an exquisite degree of target recognition in this system" (emphasis added by the board) (cf. page 401, right-hand column, lines 11 to 4 from the bottom of document D9).

In view of the evidence on file, the board is also not convinced that transgenic plant cells comprising in their genome (one or more) short (35 nucleotides) DNA fragment(s) with a low (70%) homology to the corresponding nucleotide sequence of the genomic BNYVV RNA1 exhibit a BNYVV resistance, let alone a complete BNYVV resistance.

- 18. It follows from the above considerations that the technical problem, as formulated in point 15 above, is not solved over the entire scope of claim 1 of Auxiliary Request I.
- 19. The board considers the post-published document D23 not to be prima facie relevant. The content of this document, although of a general character, concerns a specific type of RNA structure (short hairpin RNA, shorter stems RNA) and is not directly related to (BNYVV) viral resistance and/or transgenic (sugar beet) plants. Moreover, document D23 was filed only in the afternoon of the day of the oral proceedings before the board, i.e. at the latest possible stage of the present proceedings (cf. point VII supra). Thus, the board, in exercise of its discretion, decides not to admit document D23 into the appeal proceedings (Article 13(1) RPBA).

Reformulation of the technical problem

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- 20. According to the established case law, if the formulated technical problem is considered not to be successfully solved, it is then required to reformulate the problem in a less ambitious manner (cf. "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, I.D.4.4.2, page 179).
- 20.1 In the present case, starting from document D1, the objective technical problem has to be reformulated in line with the respondent's view, namely as the provision of an alternative transgenic sugar beet plant having (whatsoever) BNYVV resistance (cf. point XIV supra).
- 20.2 The solution proposed by the patent has already been described in point 16 supra. In view of the findings in points 17.1 and 17.2 above, it may be argued that doubts arise also as to whether this reformulated technical problem has actually been solved over the entire scope of the claim and whether it needs to be reformulated in even less ambitious terms, however, in view of the prior art on file (cf. point 22 infra), the board sees no reason to further elaborate on this issue.

Obviousness and expectation of success

21. Document D1 mentions publications belonging to documents of the state of the art, which disclose the transformation and expression of the BNYVV coat protein (CP) in sugar beet plants and the presence of CP-mediated BNYVV resistance in the resulting transgenic sugar beet plants (cf. page 2, line 22 to page 4, line 8 of document D1). This prior art is acknowledged with the prospect to provide a motivation for a skilled person to look for further improvements, like total

immunity and/or alternatives (cf. page 4, lines 8-24 of document D1). In doing so, document D1 refers to the BNYVV genome as consisting of five plus-sense RNAs, "two of which (RNAs 1 and 2) encode functions essential for infection of all plants" (cf. page 6, lines 3-8 of document D1). As summarized in point 14 supra, document D1 itself is concerned with the BNYVV RNA2.

22. The board takes the view that, considering this motivation, a skilled person would have taken note of BNYVV RNA1 as an obvious alternative to BNYVV CP and RNA2-mediated resistance. No hindsight is required to select BNYVV RNA1 when looking for an alternative to the subject-matter disclosed in document D1. The BNYVV RNA1 sequence, known in the art as a replicase, encodes three distinct replication-associated domains: (5', Nterminus) a methyl-transferase, a NTP-binding/helicase, and a RNA-dependent RNA polymerase (3', C-terminus) (cf. page 8, point 15.3 of the board's communication pursuant to Article 15(1) RPBA referring to the state of the art cited in the patent and in document D1). The board is convinced that a skilled person in the field of document D1 would also be well-aware of the prior art concerned with viral replicase and the relevance of a replicase-mediated resistance in transgenic plants. No hindsight is required to combine the general teaching of document D1 with the teaching of document D6, a document directly concerned with these two issues.

The fact that, as argued by the appellant (cf. point XIII supra), on the basis of the inoculation studies reported in document D1 not all TGB genes of the BNYVV RNA2 may result in BNYVV mediated resistance, would not have prevented a skilled person from considering BNYVV RNA1 as a possible alternative to BNYVV RNA2. Rather,

this information would have motivated the skilled person to identify and characterize the specific BNYVV RNA1 sequences providing the desired effect. It is noted in this context that, apart from the specific BNYVV RNA1 sequences used in Example 3 of the patent and in post-published document WO 00/68374, there is no information on file regarding the effect of any other specific BNYVV RNA1 sequences or subsequences thereof (cf. point 14.3 supra and point 27.1.iv) infra).

22.1 Document D6, a review article, already in the abstract, states that the "(t) ransformation of a plant with a DNA sequence derived from a gene encoding a viral replicase can endow it with a high level of resistance to the virus" and "(i)t is considered that expression of replicase-derived sequences at the protein level interferes with normal functioning and/or assembly of viral replicase enzyme complexes leading to a general, market inhibition of viral replication in the cells of these transgenic plants" (cf. page 339, left-hand column, first paragraph of document D6). Although transgenic plants transformed with the replicases from alfalfa mosaic virus (AIMV) and from brome mosaic virus (BMV) are not rendered resistant to virus replication, document D6 reports successful replicase-mediated resistance in transgenic plants transformed with the replicases from tobacco mosaic virus (TMV), pea earlybrowning tobravirus (PEBV), cucumber mosaic virus (CMV) and potato virus X (PVX) (cf. inter alia, page 344, right-hand column second paragraph of document D6). Indeed, document D6 concludes that "(t)ransformation of plants with sequences derived from viral replicase protein genes can cause suppression of virus replication. Replicase gene-mediated resistance offers a promising new approach" (cf. page 345, right-hand column, last paragraph of document D6).

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- This conclusion is in line with the general disclosure of document D7, an earlier published document (1988), which, although not reporting any experimental data, refers to the inhibition of virus replication by incorporation of complementary DNAs to viral genes, such as the viral replicase, in the plant host genome (cf. page 88, paragraph bridging left and right-hand columns of document D7). In this context, document D7 explicitly refers (without disclosing results) to studies with defective BNYVV RNA1 in sugar beet plants and to the relevance of these studies (cf. page 90, right-hand column, second paragraph and page 91, paragraph bridging left and right-hand columns of document D7).
- 23. The combination of the teaching in documents D1 and D6 would have led a skilled person to the subject-matter of claim 1 in an obvious manner. Moreover, in view of the minimalist character of the technical problem formulated in point 20 above, the board is also convinced that this combination would have provided a skilled person with a reasonable expectation of success as well (cf. "Case Law", supra, I.D.7.1, page 184).
- 24. Thus, Auxiliary Request I does not fulfil the requirements Article 56 EPC.

## Auxiliary Requests II to V

25. Auxiliary Requests II to V were filed in reply to the board's communication pursuant to Article 15(1) RPBA (cf. point VI supra). In the light of the situation with regard to Article 84 EPC (cf. point 26 infra), the board sees no reason to assess the admissibility of these requests.

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The term "durable resistance" is present in claim 1 of all these requests (cf. point X supra). The objection for lack of clarity raised under Article 84 EPC against the Main Request applies to, and is relevant for, all these requests (cf. point 8 supra). Thus, Auxiliary Requests II to V do not meet the requirements of Article 84 EPC.

## Admissibility of Auxiliary Request VI

- Auxiliary Request VI was filed at the oral proceedings before the board only after the board had announced its conclusions with regard to the Main Request and Auxiliary Requests I to V (cf. page 3, last paragraph to page 4, third paragraph of the "Minutes of the oral proceedings of 20 May 2014"). Thus, Auxiliary Request VI is filed late and represents an amendment of the appellant's case. According to Article 13(1) RPBA, its admissibility is at the board's discretion.
- 27.1 Claim 1 of Auxiliary Request VI results from a combination of claims 1 and 2 of Auxiliary Request I and limits the DNA fragments to fragments being "at least 90% homologous to the corresponding nucleotide sequence of the genomic RNA1" of BNYVV (cf. points IX and XI supra). This amendment addresses an objection already raised at a very early stage of the proceedings.
  - i) Document D9 was filed with the opponent's "Notice of opposition", dated 14 May 2008, and its content was discussed in the context of the length and the degree of homology of the DNA fragments used in the method of the patent (cf. point 5, paragraph bridging pages 18-19 and point 2 on pages 25-27 of "Notice of opposition").

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- ii) The objection was considered to be relevant under Articles 83 and 56 EPC, as can be seen from the communication of the opposition division issued on 20 January 2010 in preparation of the oral proceedings at first instance (cf. point 4.3, paragraph bridging pages 3-4 and point 6.3, paragraph bridging pages 4-5 of the communication of the opposition division dated 20 January 2010). The relevance of the degree of homology, although only in the context of short DNA fragments of at least 15 nucleotides, was also discussed in the decision under appeal with explicit reference to document D9 (cf. page 9, point 3.2.3 of the decision under appeal; point 17.2 supra).
- iii) Document D9 was also cited in the respondent's reply to the appellant's Grounds of Appeal, in which the respondent maintained the objections raised in the first instance (cf. pages 3-4 of the respondent's letter of 19 May 2011). In reply thereto, the appellant filed a new Main Request and Auxiliary Requests I to IV in which claim 1 of all requests referred to a 70% degree of homology (cf. point IV supra).
- iv) In the board's communication pursuant to Article 15(1) RPBA, the parties' attention was drawn to the importance of the question whether the technical problem was solved over the entire scope of the claims. In the board's opinion, it was not credible that BNYVV mediated resistance could be obtained "with each and every (long, short, specific) fragment cited in the claims" (emphasis added by the board) (cf. points 17 and 17.1 on pages 9-10, and point 19.2 on page 12 of the communication pursuant to Article 15(1) RPBA). This reference to the specificity of the DNA fragment is not only related to the specificity of the target sequence

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(an issue not further discussed in appeal proceedings; cf. point 22 *supra*) but also to the degree of homology of these fragments to the corresponding target sequence.

v) In reply to the board's communication pursuant to Article 15(1) RPBA, the appellant withdrew all former requests and replaced them by a new Main Request and new Auxiliary Requests I to V (cf. point VI supra). Claim 1 of Auxiliary Request IV defined a specific DNA fragment (nucleotides 153 to 3258 of the genomic RNA1 of BNYVV) or sequences of at least 95% homology thereto. Claim 1 of the Main Request and of Auxiliary Requests I to III referred to DNA fragments with at least 70 % homology.

Therefore, in view of the prosecution history of the present case, Auxiliary Request VI should and could have been filed at an earlier stage of the proceedings.

- 27.2 Moreover, Auxiliary Request VI is, prima facie, not considered to overcome all objections raised in the present decision. In view of the evidence on file, the board is not convinced that transgenic plant cells comprising in their genome, only and exclusively, a single DNA fragment of the BNYVV RNA1 exhibit a resistance to BNYVV (cf. point 17.1 supra).
- 28. In view thereof, the board, exercising the discretion conferred to it by Article 13(1) RPBA, decides not to admit Auxiliary Request VI into the appeal proceedings.

<u>Violation of the right to be heard (Article 113(1) EPC and Rule 106 EPC)</u>

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- 29. The board cannot comprehend the appellant being surprised at the oral proceedings by the board's reference to document D9 and the discussion on the relevance of the degree of homology of the fragments of DNA used in claim 1 (cf. point XIII supra).
- 29.1 It is apparent from the prosecution history of the present case, that both, document D9 and the importance of the degree of homology were in the focus of discussion already at a very early stage of the opposition proceedings and that this discussion continued until the very end of the written procedure before the board of appeal (cf. point 27.1 supra).
- It is also apparent from this prosecution history, that the appellant had ample opportunities, both in opposition and in appeal proceedings, to amend the claims as required to take into account the objections arising from document D9 and the low (70%) degree of homology indicated in the claims of several of the appellant's requests. Indeed, at least one of these requests, namely Auxiliary Request IV, directly addresses these objections by increasing the defined degree of homology to at least 95% homology (cf. point 27.1.v) supra).
- 29.3 It was therefore to be expected that the board would consider these objections at the oral proceedings. The board is not aware of any circumstances preventing the appellant from addressing these objections at an appropriate stage of the procedure.
- 29.4 According to established case law, it is not the purpose of an appeal proceedings to give the patentee the opportunity to recast its claims as it sees fit and to have all its requests admitted into the appeal

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proceedings - a principle mirrored in Articles 12(4) and 13(1) RPBA (cf. "Case Law", supra, IV.E.1, page 934 and IV.E.4, page 984, and, inter alia, decision T 5/08 of 10 November 2010, points 15-20 of the Reasons).

30. The board cannot see that the appellant's right to be heard has been violated as it had plenty of time and possibilities to respond to an objection that was on file since the beginning of both the opposition and the appeal procedure. Therefore, the board has no reason for changing its decision on the non-admissibility of Auxiliary Request VI into the appeal proceedings (cf. points 27 and 28 supra).

## Admissibility of Auxiliary Request VII

- 31. Auxiliary Request VII was filed at the oral proceedings only after the board had announced its conclusions on the Main Request and Auxiliary Requests I to V, on the non-admissibility of Auxiliary Request VI, and on the appellant's objection as regards a violation of its right to be heard (cf. page 4, last paragraph to page 5, fourth paragraph of the "Minutes of the oral proceedings of 20 May 2014"). Auxiliary Request VII is late filed and represents an amendment of the appellant's case. Its admissibility into the appeal proceedings is at the board's discretion (Article 13(1) RPBA).
- 31.1 Claim 1 of Auxiliary Request VII is directed to a plant cell "comprising in its genome a DNA fragment identical to nucleotides 153 to 3258 of the corresponding nucleotide sequence of the genomic RNA 1 of said [BNYVV] virus" (cf. point XI supra), i.e. the specific DNA fragment used in the examples of the patent (cf. page 5, paragraph [0039] of the patent). None of the

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appellant's requests filed at the first instance proceedings was limited to this specific subject-matter. This subject-matter was not present in any of the appellant's requests maintained with its statement of Grounds of Appeal or filed in reply to the respondent's reply thereto.

- 31.2 This subject-matter was presented, for the first time in the proceedings, in claim 2 of Auxiliary Request V filed by the appellant in reply to the board's communication pursuant to Article 15(1) RPBA (cf. point VI supra). However, the board has not decided on the admissibility of Auxiliary Request V since, at first glance, claim 1 of this request lacked clarity (Article 84 EPC; cf. points X and 25-26 supra).
- Also with regard to this request, it is apparent from the prosecution history of the case, that the appellant had ample opportunities, both in opposition and in appeal, to file a request restricted to the specific subject-matter of Auxiliary Request VII. The late filing of this request is not in line with the purpose of an appeal proceedings (cf. point 29.4 supra).
- 31.4 Moreover, Auxiliary Request VII is, prima facie, not considered to overcome all objections raised in the present decision. In view of the evidence on file, the board is not convinced that transgenic plant cells comprising in their genome, only and exclusively, a single DNA fragment of the BNYVV RNA1 exhibit a resistance to BNYVV (cf. point 17.1 supra). It is noted that some of the amendments introduced into claim 1 of Auxiliary Request V (which does not form part of present Auxiliary Request VII), for instance the feature "wherein said transgenic sugar beet plant contains 2 or 3 bands in a Southern blot for the

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presence of said DNA fragment", were introduced with the intention to address this issue. This shows that the appellant, well in advance of the oral proceedings, was well-aware of the relevance of this objection.

32. In view thereof, the board, exercising the discretion conferred to it by Article 13(1) RPBA, decides not to admit Auxiliary Request VII into the appeal proceedings

#### Order

## For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated