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**Datasheet for the decision  
of 19 December 2013**

**Case Number:** T 0657/10 - 3.3.08

**Application Number:** 99928700.6

**Publication Number:** 1086236

**IPC:** C12N15/82

**Language of the proceedings:** EN

**Title of invention:**

POLYUNSATURATED FATTY ACIDS IN PLANTS

**Patent Proprietor:**

Calgene LLC

**Opponents:**

BASF Plant Science GmbH  
Bayer S.A.S.

**Headword:**

Stearidonic plant delta desaturases/CALGENE

**Relevant legal provisions:**

EPC Art. 113(1), 114, 83  
EPC R. 103  
RPBA Art. 12(4), 13(1)

**Keyword:**

Substantial procedural violation (no); Reimbursement of appeal fee (no)

Sufficiency of disclosure

- Main Request and Auxiliary Requests 1 to 6 (no)

Admissibility of new documentary evidence (no); Admissibility of Auxiliary Requests 7 and 8 (no)

**Decisions cited:**

G 0009/91, G 0010/91, G 0001/03, T 0737/96, T 1231/01,  
T 0645/02, T 2239/08, T 0775/08

**Catchword:**

Sufficiency of disclosure of elite events (see points 12.1 to 12.4 of the Reasons)



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Case Number: T 0657/10 - 3.3.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.08**  
**of 19 December 2013**

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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
26 January 2010 concerning maintenance of the  
European Patent No. 1086236 in amended form.**

**Composition of the Board:**

**Chairman:** M. Wieser

**Members:** P. Julià

D. Rogers

## Summary of Facts and Submissions

- I. Two oppositions were filed against European patent No. 1 086 236 on the grounds of Articles 100(a), (b) EPC. The opposition division considered the Main Request (claims as granted) and Auxiliary Request 1 (filed on 11 February 2009 as Auxiliary Request 2) to contravene Articles 54 and 56 EPC, respectively. Auxiliary Request 2 (filed on 2 December 2009 at the oral proceedings before the opposition division) was considered to fulfil all requirements of the EPC and, accordingly, the patent was maintained on the basis of this request.
- II. Appeals against the decision of the opposition division were lodged by the patentee and the opponents 01 and 02 (appellants I, II and III, respectively).
- III. With the statement of Grounds of Appeal, appellant I maintained, as its Main Request, the claims as granted and filed new Auxiliary Requests 1 to 3.
- IV. In their statement of Grounds of Appeal, appellants II and III referred to the findings of the opposition division to admit the late-filed document D20 (*infra*) into the opposition proceedings and argued that their right to be heard was violated (Article 113(1) EPC). Therefore, they requested the reimbursement of the appeal fee. Objections raised under Articles 100(a) and (b) EPC were maintained and both appellants II and III requested the revocation of the patent in its entirety. Appellant III filed also document D21 (*infra*) in support of its arguments.
- V. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), annexed to the summons to oral proceedings, the board

informed the parties of its preliminary opinion on the issues to be discussed at the upcoming oral proceedings.

- VI. In reply to the communication of the board, appellant I filed Auxiliary Requests 4 to 6 and document D22 (*infra*). Auxiliary Request 5 was identical to the claim request upheld by the opposition division. Appellant II did not reply to the board's communication and appellant III announced its presence at the scheduled oral proceedings but did not file substantive submissions.
- VII. Oral proceedings took place on 19 December 2013 in the presence of all parties. During these proceedings, appellant I filed Auxiliary Requests 7 and 8.
- VIII. Claims 1-2, 6, 10-13 and 16-17 of the **Main Request** (claims as granted) read:

"1. A method for producing stearidonic acid in a plant seed, said method comprising growing a plant having integrated into its genome a first DNA construct comprising, in the 5' to 3' direction of transcription, a promoter functional in a plant seed cell, a DNA sequence encoding a delta-six desaturase, and a transcription termination region functional in a plant cell, and a second construct comprising in the 5' to 3' direction of transcription, a promoter functional in a plant seed cell, and a DNA sequence encoding a delta 15-desaturase and growing said plant under conditions whereby said delta-six desaturase and said delta 15-desaturase are expressed."

"2. The method of claim 1, wherein said plant has a third construct integrated into its genome, wherein

said third construct has in the 5' to 3' direction of transcription, a promoter functional in a plant seed cell, and a DNA sequence encoding a delta 12 desaturase."

"6. The method of claim 1, wherein said method further comprises extracting oil from said plant seed."

"10. The method of claim 6, wherein said oil comprises about 20 weight percent or greater stearidonic acid."

"11. The method of claim 6, wherein said oil comprises about 25 weight percent or greater stearidonic acid."

"12. A transgenic plant or a seed thereof having integrated into its genome a first DNA construct comprising, in the 5' to 3' direction of transcription, a promoter functional in a plant seed cell, a DNA sequence encoding a delta-six desaturase, and a transcription termination region functional in a plant cell, and a second construct comprising in the 5' to 3' direction of transcription, a promoter functional in a plant seed cell, and a DNA sequence encoding a delta 15-desaturase, which is capable of delta-six desaturase and delta 15-desaturase expression and of producing seed oil containing stearidonic acid."

"13. The seed of the plant of claim 12 comprising about 5 weight percent or greater stearidonic acid as a component of total fatty acids found in the seed oil."

"16. The seed of claim 13 comprising about 20 weight percent or greater stearidonic acid as a component of said seed oil."

"17. The seed of claim 13 comprising about 25 weight percent or greater stearidonic acid as a component of said seed oil."

Claims 3-5 and 7-9 were directed to preferred embodiments of claims 1 and 6, respectively. Claims 14-15 were directed to preferred embodiments of claim 13. Claim 18 was directed to a seed oil obtained from a seed of claims 13-17. Claim 19 was directed to a plant seed tissue of a transgenic plant of claim 12 comprising a seed oil as defined in claims 13-17.

- IX. Claims 1-2, 6, 10-13 and 16-17 of **Auxiliary Requests 1 and 4** were identical to those of the Main Request (*supra*). Claims 1-2, 6, 10, 12-13 and 16 of **Auxiliary Requests 2 and 3** were also identical to those of the Main Request (*supra*). **Auxiliary Request 5**, the request upheld by the opposition division, was identical to the Main Request except for the deletion of all claims related to a content of stearidonic acid (SDA) of about 25 weight percent or greater (claims 11 and 17 of the Main Request) and the claim directed to a seed oil (claim 18 of Main Request). **Auxiliary Request 6** was identical to Auxiliary Request 5 except for the fact that the DNA sequences encoding the delta desaturases in claims 1-2 (method for producing SDA in a plant seed) and 11 (transgenic plant or seed thereof) were defined as being "heterologous DNA sequences".
- X. The **Auxiliary Requests 7 and 8** were identical to Auxiliary Requests 5 and 6, respectively, except for the deletion of all claims related to a content of SDA of about 20 weight percent or greater.
- XI. The following documents are cited in this decision:



D9: WO-A2-96/21022 (publication date: 11 July 1996);

D20: US-B2-7,622,632 (publication date:  
24 November 2009);

D21: H. Chu and T.C. Tso, *Plant Physiol.*, 1968, Vol.  
43, pages 428 to 433;

D22: H. Eckert et al., *Planta*, 2006, Vol. 224, pages  
1050 to 1057.

XII. The submissions made by appellant I (patentee), insofar as they are relevant to the present decision, may be summarized as follows:

*Substantial procedural violation and reimbursement of appeal fees*

No submissions were filed, and none were put forward at the oral proceedings before the board, as regards this issue.

*Admissibility of documents D21 and D22*

Document D21 was late filed and did not provide any information that was not already on file. Document D22 was filed in direct reply to the board's communication in which concerns were expressed regarding a relevant issue under Article 83 EPC, namely whether the presence of three constructs integrated into the plant genome was an essential feature of the invention.

*Main Request - Article 100(b) EPC/Article 83 EPC*

The gist of the invention was the provision of a method for obtaining recombinant plants with an amount of SDA

higher than the wild-plants. The method relied on the integration into the plant genome (and the expression) of DNA constructs encoding two ( $\Delta 6$ ,  $\Delta 15$ ) or three ( $\Delta 6$ ,  $\Delta 15$ ,  $\Delta 12$ ) delta-desaturases. The patent was not directed to the optimization of this method and did not intend to be limited to certain (integration) elite events but it rather disclosed a basic concept that allowed further technical developments. This was shown indeed by the results given in the examples. Although the integration into a plant genome was a random phenomenon, a significant increase in the SDA content was present in all events, independently of whether the DNA constructs encoded only two ( $\Delta 6$ ,  $\Delta 15$ ) or three ( $\Delta 6$ ,  $\Delta 15$ ,  $\Delta 12$ ) delta desaturases, whether a single (with all desaturases) or several DNA constructs, whether a crossing of recombinant plants (with desaturases in different DNA constructs) or whether the transformation of a single plant (with a single or several DNA constructs), were used.

Even if not all recombinant plants and seeds displayed a content of 20-25% SDA, some did, and it was well within the ability of a skilled person to screen hundreds of transgenic plant events and seeds in order to identify those displaying such SDA content. Evidence was on file showing that a 20-25% SDA content was obtained in several recombinant (canola, soybean) plants transformed by a single T-DNA vector with DNA constructs encoding two ( $\Delta 15$ ,  $\Delta 6$ ) or three ( $\Delta 15$ ,  $\Delta 6$ ,  $\Delta 12$ ) delta desaturases (Examples 10-11 of document D20) or by crossing recombinant plants, one plant with a DNA construct encoding two ( $\Delta 6$ ,  $\Delta 12$ ) delta desaturases and another plant with a DNA construct encoding the third ( $\Delta 15$ ) delta desaturase (Example 2 of the patent). Means and tools to carry out all these embodiments were disclosed in the patent and shown to be effective in

both the patent and in post-published documents on file, such as document D20. The skilled person would have encountered no technical problems when performing all these embodiments, when testing the resulting recombinant plants and screening and selecting those recombinant plants with a high SDA content.

The core of the opponents' objection relied on an alleged absence of essential features in claim 1 and on the fact that, in the opponents' view, claims with subject-matter related to a high SDA content were drafted in terms of the result to be achieved. These objections could be, if at all, relevant under Article 84 EPC (not a ground for opposition) but not under Article 83 EPC.

*Admissibility of Auxiliary Requests 7 and 8*

The amendments introduced into these requests were a mere deletion of dependent claims, namely those with the most specific subject-matter. The amendments were not directed to the gist of the invention, did not introduce new technical features or subject-matter into the appeal proceedings and could have been expected by the other parties. The filing of these requests at an earlier stage of the appeal proceedings would have unnecessarily overloaded the board. Although late filed, these requests were fully justified by, and appropriate to, the course of the appeal proceedings.

XIII. The submissions made by appellants II and III (opponents 01 and 02, respectively), insofar as they are relevant to the present decision, may be summarized as follows:

*Substantial procedural violation and reimbursement of appeal fees*

Document D20 was filed only at the oral proceedings before the opposition division. Although it was already available to the patentee at an earlier time, no reasons were provided to explain why it was not filed earlier in the proceedings. It addressed an issue that had been on file from the beginning of the opposition proceedings, namely the absence of experimental data in the patent showing that the claimed subject-matter was an effective solution of the objective technical problem. The content of this document was, however, not relevant, since it related to embodiments that did not fall within the scope of the claims. The document was long and complex and, by filing it at the oral proceedings, the opponents were deliberately deprived of the opportunity to study its content in detail. Thereby, they were put at an unacceptable disadvantage and their right to be heard was infringed (Article 113(1) EPC).

*Admissibility of documents D21 and D22*

Document D21 was filed at the earliest stage of the appeal proceedings, namely with the Grounds of Appeal. The document addressed an issue raised in the decision under appeal and merely illustrated the common general knowledge in the field. Document D22 was late filed and should be disregarded.

*Main Request - Article 100(b) EPC/Article 83 EPC*

Both the patent and the post-published documents on file showed that recombinant plants with high SDA content could only be obtained by using very particular

constructs and specific conditions. Recombinant plants with high SDA content could be obtained by using DNA constructs encoding two ( $\Delta 15$ ,  $\Delta 6$ ) delta desaturases only when both desaturases were in a single T-DNA vector and the recombinant plants had an endogenous ( $\Delta 12$ ) delta desaturase. All three ( $\Delta 6$ ,  $\Delta 12$ ,  $\Delta 15$ ) delta desaturases were necessary for obtaining a high SDA content. This was possible only when very specific delta desaturase genes and particular plant promoters were used that were known to be highly efficient. However, none of these specific features was present in broad claim 1.

Both the patent and the post-published documents on file showed that, even when using optimal constructs and conditions, recombinant plants and seeds having the highest SDA content cited in the claims were very rarely obtained. Indeed, the patent referred only to a single event having a SDA content greater than 25% and in Table 10 of the post-published document D20 only one event with a SDA content of 20% was reported. These rare elite events could not provide an adequate basis for an allowable generalization. The integration of DNA constructs into the genome of a plant was a random phenomenon. Thus, the obtention of rare elite events relied on chance only and could not be reliably reproduced without undue burden.

*Admissibility of Auxiliary Requests 7 and 8*

These requests addressed objections that were raised at the beginning of the opposition proceedings. They were repeated in the statements of Grounds of Appeal and were considered by the board to be relevant in its communication pursuant to Article 15(1) RPBA. The

patentee had had ample opportunity to file these requests at a much earlier stage of the proceedings.

- XIV. Appellant I (patent proprietor) requested that the decision under appeal be set aside and, as a Main Request, that the patent be maintained as granted, or alternatively that the patent be maintained on the basis of any of Auxiliary Requests 1-8.
- XV. Appellants II and III (opponents 01 and 02, respectively) requested that the decision under appeal be set aside and that the patent be revoked. Furthermore, they requested that their appeal fees be reimbursed.

### **Reasons for the Decision**

#### *Substantial procedural violation and reimbursement of appeal fees*

1. According to the case law established by the Boards of Appeal, if the way in which a department of first instance has exercised its discretion on a procedural matter is challenged in appeal, it is not the function of a board of appeal to review all the facts and circumstances of the case as if it were in the place of the department of first instance. A board should only overrule the way in which a department of first instance has exercised its discretion if the board concludes it has done so according to the wrong principles, or without taking into account the right principles, or in an unreasonable way (cf. "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, IV.E.3.6, page 983).

2. Document D20 was filed at the oral proceedings before the first instance and admitted into the opposition proceedings by the opposition division on the grounds of its *prima facie* relevance (cf. page 7, point 3.5 of the decision under appeal). Thus, the opposition division exercised its discretion in favour of the patent proprietor. When the board assesses whether the opposition division exercised its discretion in accordance with the right principles, the following points are of relevance:
  - 2.1 According to the "Minutes of the oral proceedings before the opposition division" (hereinafter the "*Minutes*"), the contents of document D20 were discussed at the oral proceedings in the context of Article 56 EPC (cf. pages 6-7 of the Minutes). There is no indication in the Minutes that any of the opponents requested an interruption of the oral proceedings or a postponement of these proceedings for studying the contents of document D20 and there is certainly no indication that such a request was refused by the opposition division.
  - 2.2 It may be arguable whether the contents of document D20 are long and complex. However, the experiments and data reported in document D20 are similar to those disclosed in the patent-in-suit and do not diverge from those usually reported in this technical field. Moreover, according to the Minutes, none of the parties had any problem to identify the relevant disclosure in document D20 and its relevance as regards the claimed subject-matter (cf. pages 6-7 of the Minutes).
  - 2.3 The contents of document D20 were in fact a reason for the opposition division to consider the first Auxiliary Request in opposition proceedings not to fulfil the

requirements of Article 56 EPC (cf. pages 11-12 of the decision under appeal). This confirms the *prima facie* relevance of the document referred to by the opposition division as a reason for its admissibility into the proceedings (cf. point 2 *supra*).

2.4 Indeed, the contents of document D20 were referred to in the statement of Grounds of Appeal of both appellants II and III in the context of Articles 56 and 83 EPC (cf. pages 13-16 and pages 9-11 of the Grounds of Appeal of appellant II and III, respectively). Likewise, the board discussed the contents of this document in its communication pursuant to Article 15(1) RPBA and noted its relevance under Article 83 EPC (cf. page 10 of the board's communication). The teaching of document D20 is also considered in the present decision (cf. point 9.3 *infra*). There are thus no doubts on the relevance of this document.

3. In the light of the above considerations, the board considers that the opposition division did not contravene the requirements of Article 113(1) EPC and exercised its discretion in accordance with the right principles set out in Article 114(1) EPC (cf. G 9/91 and G 10/91, OJ EPO 1993, pages 408 and 420, respectively). There is no evidence proving a procedural violation, let alone a substantial one. The requests of appellants II and III for reimbursement of their appeal fees are therefore refused (Rule 103 EPC).

#### *Admissibility of documents D21 and D22*

4. With its statement of Grounds of Appeal, appellant III filed document D21. The document was cited in the context of Article 56 EPC for illustrating an issue of



the common general knowledge in the field. This issue was already addressed during the opposition proceedings and prior art document D9 was cited for supporting the very same argument (cf. page 8, point III of the decision under appeal). The board considers the contents of document D21 not to be more relevant than those of document D9 and thus, does not see a reason for admitting this late filed document into the appeal proceedings. The less so, in view of the publication date of document D21 (1968) and the fact that no convincing reasons have been given to explain why it could not have been filed at an earlier stage of the proceedings.

5. In its reply to the board's communication, appellant I filed document D22 arguing that the contents of this document addressed an issue raised by the board in its communication (cf. point XII *supra*). However, this specific issue was already addressed and discussed during the opposition proceedings and appellant I had had ample opportunity to file this document at an earlier stage of the proceedings. No reasons have been provided to explain why it was not filed earlier in the proceedings. Moreover, the board considers the contents of document D22 not to be more relevant than those of other documents on file, such as document D20 (cf. point 9.3 *infra*).
6. Thus, the board, exercising its discretion under Article 12(4) RPBA, decides not to admit documents D21 and D22 into the appeal proceedings.

*Main Request*

*Articles 123(2), (3) and 84 EPC*

7. The Main Request in appeal and in opposition proceedings are the same, namely the maintenance of the patent on the basis of the claims as granted (cf. point VIII *supra*). Thus, Articles 123(3) and 84 EPC are not open for the board to examine. The same applies to Article 123(2) EPC since Article 100(c) EPC was not a ground of opposition.

*Article 100(b) EPC/Article 83 EPC*

8. The invention relates to a method for modulating the levels of enzymes and/or enzyme components capable of altering the production of long chain polyunsaturated fatty acids (PUFAS) in a host plant (cf. page 2, paragraph [0001] of the patent). This method relies on the integration into the genome of host plants of DNA constructs comprising DNA sequences encoding specific delta desaturases involved in PUFA biosynthesis (cf. page 3, paragraph [0008] of the patent). The enzymes involved in PUFA biosynthesis and the PUFA biosynthetic pathway are known in the prior art and described in the patent (cf. page 2, paragraph [0006] and Figures 1-2 of the patent). The relevant enzymes for the teachings of the patent are delta desaturases, in particular, the  $\Delta 6$ ,  $\Delta 12$  and  $\Delta 15$  desaturases (cf. *inter alia*, page 3, paragraph [0010], page 5, paragraphs [0015]-[0016], page 6, paragraph [0021] of the patent). The claimed subject-matter is limited to particular embodiments relating only to stearidonic acid (SDA). Claim 1 relates to a method for producing SDA which comprises the integration into a plant genome of a first and a second DNA construct encoding a  $\Delta 6$  and a  $\Delta 15$  desaturase, respectively. Claim 2 contemplates the integration of a third DNA construct encoding a  $\Delta 12$  desaturase. The resulting transgenic plants and seeds thereof as well as plant seed tissues and seed oil

obtained from these seeds are also subject-matter of the Main Request (cf. point VIII *supra*).

9. The claimed subject-matter is exemplified in Example 2 of the patent, which reports two different sets of experiments.

9.1 In the first set, transgenic canola (*Brassica*) plants containing a DNA construct with a  $\Delta 15$  desaturase from *B. napus* and the napin 5'- and 3'-regulatory regions (PCGN5558) are crossed with transgenic canola plants containing a DNA construct with  $\Delta 6$  and  $\Delta 12$  desaturases from *Mortierella alpina* and the napin 5'- and 3'-regulatory regions (PCGN5544, which construction is disclosed in Example 5 of the patent). The F1 seeds are analyzed for SDA content and the results are shown in Table 1 (cf. page 10, line 18 to page 14 of the patent).

In Table 1, the results for 39 strains are disclosed. The great majority thereof (31) have levels of SDA (18:4) lower than 10% (13 lower than 4%, and 9 between 4-5%). There are three strains with SDA levels between 10-15% and two strains between 15-18%. There is only one strain with 25.21% and one with 23.45%.

9.2 In the second set of experiments, the *B. napus*  $\Delta 15$  desaturase is combined with the  $\Delta 6$  and  $\Delta 12$  desaturases from *M. alpina* to form three napin transcriptional units on one T-DNA for transformation (PCGN5561). The SDA content of pooled T2 seeds obtained from *Brassica* plants with this construct are shown in Table 2 of the patent (cf. page 15 of the patent).

In Table 2, the results of 10 strains are disclosed. All of them have a SDA content lower than 8%. There is

only one strain with a level higher than 7%, all other strains have a content of SDA lower than 5%.

9.3 These results are comparable with those reported in post-published document D20 (cited as expert opinion). In Example 10, canola plants are transformed with a DNA construct (pMON77216) containing the  $\Delta 15$  desaturase from *Neurospora crassa* with the  $\Delta 6$  and  $\Delta 12$  desaturases from *M. alpina* under the control of the napin promoter (cf. columns 31-34 and Figure 7G of document D20). In Table 6, the SDA content of 10-seed pools from R1 plants is shown. None of the 75 identified events has a SDA content higher than 20% and there is only one event higher than 15% (17.95). There are two events with a SDA content higher than 11% (13.31, 11.01) and five between 10-11%. The great majority (52 events) have a SDA content lower than 7% and, 37 thereof even lower than 5%.

Since in some of these lines the  $\Delta 12$  desaturase was partially deleted, further data from single seeds of a specific event (BN\_G1190) are reported (Table 7) as well as of R1 seed pools resulting from the re-transformation of homozygous  $\Delta 16$ ,  $\Delta 12$  plant lines with a construct containing the  $\Delta 15$  desaturase (Table 8). None of the results reported shows a SDA content of 19% (the highest values reported are 18.59, 17.95) and, for the re-transformation plants, only two lines, out of 11, have a SDA content higher than 10% (17.95, 11.19), the majority (7) being lower than 5%.

Similar results are disclosed in Example 11 of document D20, in which canola plants were transformed with a DNA construct (pMON77215) containing only the *N. crassa*  $\Delta 15$  desaturase and the *M. alpina*  $\Delta 6$  desaturase under the control of the napin promoter (cf. columns 34-36,

Figure 7F of document D20). In Table 9, all 39 events shown have a SDA content lower than 15% and for the great majority (29) the SDA content is lower than 10%. Even the specifically selected event BN\_G1860 has a maximum SDA content lower than 20% (19.23) as shown in Table 10.

10. The results shown in the Examples of the patent, which are in line with those of post-published document D20, exemplify and support the general gist of the invention as argued by appellant I (cf. point XII *supra*). The claimed subject-matter, however, comprises specific embodiments requiring a SDA content of 20 or 25 weight percent or even greater. As shown in the patent and in post-published document D20, this SDA content falls significantly outside the average SDA content obtained for the great majority of the reported events. Indeed, it is very rarely achieved and, if at all, derived from an extraordinary and thus surprising event. Such events are known in the art as "elite events" and, as such, are also acknowledged in the jurisprudence of the Boards of Appeal (cf. point 12 *infra*).
11. According to Article 83 EPC, the patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In particular, the disclosure of the patent must enable a skilled person to carry out all claimed embodiments and thus, in the present case, those embodiments concerned with "elite events".
  - 11.1 It is worth noting that this requirement is also of relevance under Article 56 EPC since, as established in the case law of the Boards of Appeal, all claimed embodiments must be a *bona fide* solution of the objective technical problem or, in other words, the

problem must be credibly solved over the whole scope of the claims. According to decision G 1/03 (OJ EPO, 2004, page 413, point 2.5.2 of the Reasons), "*if 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*".

11.2 In the present case, the effect is expressed in all claims directed to an "elite event", i.e. claims requiring a SDA content of about 20 or 25 weight percent or greater. Thus, even though these claims in the decision under appeal were discussed under Article 56 EPC in the context of whether it was credible that the objective technical problem underlying them was actually solved (cf. page 11 to 12 of the decision under appeal), they have to be considered under Article 83 EPC. The parties were informed of the board's view in the communication pursuant to Article 15(1) RPBA (cf. point V *supra*).

12. There is ample jurisprudence of the Boards of Appeal on "elite events". According thereto, an "elite event" is defined as a particular event resulting from a random method (for which the expectations always range from nil to high) and having at least one surprising, advantageous property.

12.1 Although the specific random methods (random genome insertion, random mutagenesis, etc.) and resulting products with (normal) average properties may well be known in the prior art, the presence of a particular product with an unexpected advantageous property, i.e. containing "elements of surprise", may justify the recognition of an inventive step. This jurisprudence on "elite events" is not limited to transgenic plants (cf.

*inter alia*, T 2239/08 of 10 January 2013, points 14 and 15 of the Reasons, T 775/08 of 1 February 2011, points 12 and 12.4 of the Reasons) but it has been applied in several other fields, such as those relating to monoclonal antibodies and to the isolation of specific virus strains or (yeast) microorganisms (cf. *inter alia*, T 645/02 of 16 July 2003, points 7 to 9 of the Reasons, T 1231/01 of 14 September 2005, point 11 of the Reasons, T 737/96 of 9 March 2000, points 10, 11 and 17 of the Reasons).

12.2 As a common denominator to all cases underlying these decisions, the disclosure of the patent and/or of the patent application has to enable a skilled person to obtain the particular product resulting from the "elite event" without the need to repeat the random method *de novo*, be it by a deposit of said product (microorganism, monoclonal antibody, etc.) or by a disclosure of structural features or elements of said product (such as flanking sequences of the genome insertion site, specific mutated nucleic acid sequence, etc.). In other words, the disclosure of the patent or patent application is sufficient for a skilled person if he/she can obtain the particular product without having to rely on pure chance again, i.e. on the screening and selection of random natural events. If this is the case the requirements of Article 83 EPC are considered to be fulfilled.

12.3 In the present case, however, these requirements are not fulfilled by the disclosure of the patent-in-suit. In the second set of experiments reported in Example 2 of the patent (one T-DNA with three delta desaturases for transformation), none of the pooled T2 seeds has a SDA content higher than 8% and thus, all of them are within the average SDA content and not the result of a

surprising "elite event" as defined in the case law (cf. point 9.2 *supra*). It is only in the first set of experiments in Example 2 that two strains, out of 39, are reported to have a SDA content higher than 20%. These strains are obtained by crossing two specific transgenic plants, namely PCGN5558 ( $\Delta 15$  desaturase) transformed plants with PCGN5544 ( $\Delta 6$ ,  $\Delta 12$  desaturases) transformed plants (cf. point 9.1 *supra*). However, no information is given on the criteria used for their selection nor on the genome insertion sites characterizing each of them. Likewise, there is no information at all on the specific genome insertion sites characterizing the two specific strains or "elite events" resulting from the (random) crossing of the two parental transformed plants or of any other alternative structural feature that could enable a skilled person to obtain them again without relying on pure chance.

12.4 Moreover, none of the prior art documents on file, and in particular not document D20, provides the means and tools for a skilled person to overcome the deficiencies in the disclosure of the patent-in-suit. Firstly, as summarized in point 9.3 *supra*, none of the strains and/or events identified in document D20 has a SDA content of 20-25% or greater and, secondly, the nature of the disclosure of this document is in all relevant points similar to that of the patent-in-suit, i.e. there is no characterization of any genome insertion site or any other alternative structural feature for any of the strains and/or events reported in document D20.

13. In view of the above considerations and of the substantial deficiencies under Article 83 EPC in the disclosure of the patent-in-suit, the board sees no reason to examine in detail the objection raised by appellants II and III concerning the absence of



elements and/or features in the claims that are allegedly essential for obtaining the desired effect, i.e. a high SDA content (cf. point XIII *supra*). Likewise, there is no need for the board to consider appellant I's counter argument that this objection may be of relevance under Article 84 EPC but not under Article 83 EPC (cf. point XII *supra*).

14. Thus, the requirements of Article 83 EPC are not fulfilled for the Main Request.

*Auxiliary Requests 1 to 6*

15. All these auxiliary requests comprise claims referring to subject-matter and/or embodiments falling directly within the above definition of an "elite event", namely a transgenic plant or seed with a SDA content of 20-25% or greater (cf. point 10 *supra*). In view of the conclusion achieved above for the Main Request, the requirements of Article 83 EPC are not fulfilled for any of these Auxiliary Requests. Thus, there is no need for the board to enter into consideration of whether these Auxiliary Requests can be admitted into the appeal proceedings (Articles 12(4) and 13(1) RPBA), and whether the objections raised by appellants II and III as regards Articles 123(2) and 84 EPC are of any relevance.

16. Auxiliary Requests 1 to 6 do not meet the requirements of Article 83 EPC.

*Admissibility of Auxiliary Requests 7 and 8*

17. Claims directed to a SDA content of 20-25% or greater had already been objected at the beginning of the opposition proceedings (cf. page 10, point 4 of

opponent 01/appellant II's Grounds of opposition on 5 June 2008 and page 3, point 2.1 of opponent 01/appellant II's letter of 2 October 2009). In the decision under appeal, the opposition division considered that, whereas it was credible that about 20% SDA in seed oil could be produced with the claimed method and/or from the claimed plants, this was not the case for 25% SDA or greater. This was the reason for the opposition division not to acknowledge the requirements of Article 56 EPC for the first Auxiliary Request (cf. page 11, last paragraph to page 12, third paragraph of the decision under appeal).

18. This decision was appealed by the patentee/appellant I which, with its statement of Grounds of Appeal, maintained, as its Main Request, the claims as granted and filed new Auxiliary Requests 1 to 3 (cf. point III *supra*). Claims with subject-matter related to a SDA content of 20-25% were present in all these requests. None of these requests was limited to subject-matter with a SDA content of 20% or lower. Appellant I did not even file or maintain the second Auxiliary Request on which the opposition division decided to maintain the patent and which was limited to this subject-matter. Also subject-matter related to a SDA content of 20% or higher was objected to by appellants II and III in their statements of Grounds of Appeal (cf. page 13, point 3.2.3 and page 11, point 6 in the statements of Grounds of Appeal of appellants II and III, respectively; points XII and XIII *supra*).

19. In its communication pursuant to Article 15(1) RPBA, the board informed the parties of its preliminary opinion, namely that the objections raised against subject-matter related to a SDA content of both 20 and 25% or greater were considered to be relevant (cf. page

- 9, point 11.2 to page 10, point 13 under Article 83 EPC and page 16, point 17.2 under Article 56 EPC of the board's communication; point V *supra*). In reply thereto, appellant I filed Auxiliary requests 4 to 6, all of them still comprising the contested subject-matter (cf. points VI and IX *supra*).
20. Thus, at the beginning of the oral proceedings before the board, the only claim requests on file contained claims referring to subject-matter relating to a SDA content of about 20-25% or greater. It was only after discussion of this issue and the announcement of the board's decision that appellant I filed Auxiliary Request 7 and 8 in which all claims relating to the contested subject-matter had been deleted (cf. point X *supra*).
21. There is no doubt that Auxiliary Requests 7 and 8 are late filed in the appeal proceedings. The filing of these requests represents an amendment of appellant I's case which may be admitted and considered only at the board's discretion (Article 13(1) RPBA).
- 21.1 In view of the actual course of the appeal procedure, the board does not see any reason why appellant I could not have filed Auxiliary Requests 7 and 8 at a much earlier stage of the proceedings. The deletion of the contested subject-matter represents an important substantive amendment of an issue that always was at the core of both the opposition and the appeal proceedings, as shown in points 17 to 20 *supra*. The deletion of this subject-matter shifts the subject of these proceedings in an essential and relevant manner. The introduction of such a substantive amendment of the claim requests at a very late stage of the appeal proceedings may, on the one hand, confer an unwarranted

advantage to the patentee/appellant I and, on the other hand, unfairly disadvantages the other parties.

21.2 Although appellant I's intention may have been not to overload the board with the filing of an unnecessarily large number of requests, this cannot be a reason to excuse the late filing of requests which, in the appellant I's view, are best suited to support its case.

21.3 As for appellant I's argument that both appellants II and III could not have been surprised by such amendment because it was to be fully expected (cf. point XII *supra*), the board considers this to be highly questionable in view of the actual course of the opposition and the appeal proceedings as described in points 17 to 20 *supra*. In any case, if there was a reason for appellants II and III to expect such amendment, the same reason was also present for appellant I to have earlier filed requests comprising this amendment.

22. Thus, the board, exercising its discretion under Article 13(1) RPBA, decides not to admit Auxiliary Requests 7 and 8 into the appeal proceedings.

**Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The requests for reimbursement of the appeal fees are rejected.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated