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D E C I S I O N
of 22 October 2004

Case Number: T 1120/00 - 3.3.8

Application Number: 91909981.2

Publication Number: 0537178

IPC: C12N 15/53

Language of the proceedings: EN

Title of invention:
Nucleotide sequence of soybean stearoyl-ACP desaturase gene

Patentee:
E.I. DU PONT DE NEMOURS AND COMPANY

Opponent:
Calgene LLC

Headword:
Soybean desaturase/DU PONT

Relevant legal provisions:
EPC Art. 123(2)(3), 54(3)(4)

Keyword:
"Main request, auxiliary requests 1 and 2 - novelty (no)"
"Auxiliary request 3 - added subject-matter (no)"
"Extension of protection (no)"
"Novelty (yes)"

Decisions cited:
G 0004/93, G 0002/98, G 0001/99, G 0001/03, T 0522/99, T 1099/99, T 1070/00

Catchword:
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Case Number: T 1120/00 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.3.8
of 22 October 2004

Appellant I: (Proprietor of the patent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 18 September 2000 concerning maintenance of European patent No. 0537178 in amended form.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julia
S. C. Perryman

Summary of Facts and Submissions

I. Appeals were lodged by both the patentee (appellant I) and the opponent (appellant II) against the decision of the opposition division to maintain the European patent No. 0 537 178 (claiming priority from US 529,049 of 25 May 1990) in amended form on the basis of an auxiliary request filed on 5 June 2000. The main request was refused under Article 123(2) EPC because the introduced disclaimer was considered not to exclude the complete disclosure of a document cited under Article 54(3)(4) EPC.

II. Appellant I filed further observations in reply to the statement of the grounds of appeal of appellant II.

III. The Board sent a communication to the parties drawing their attention to referrals T 507/99 of December 2002 and T 451/99 of 14 March 2003 under Article 112(1)(a) EPC to the Enlarged Board of Appeal concerning the admissibility under Article 123(2) EPC of a disclaimer not supported by the application as filed. The Board indicated its intention of suspending the proceedings until a decision thereon was issued, unless appellant I was prepared to submit only requests avoiding the use of disclaimers.

IV. Appellant I informed the Board that it did not intend to submit only requests which avoided the use of disclaimers.

V. After decision G 1/03 of 8 April 2004 (OJ EPO 2004, 413) was issued, the parties were summoned to oral proceedings and, in a communication annexed thereto, the Board informed them of its preliminary opinion pursuant to Article 11(1) RPBA.

VI. Both parties submitted observations in reply to the Board's communication. Appellant I further filed auxiliary request 2 on 22 September 2004.

VII. Oral proceedings took place on 22 October 2004 and during the proceedings, appellant I filed auxiliary request 3.

VIII. The **main request** was identical to the main request of the contested decision and had been refiled with the statement of grounds of appeal on 29 January 2001. Claims 1, 3 to 5 and claim 7 read as follows:

"1. An isolated nucleic acid fragment comprising a nucleotide sequence encoding the soybean seed stearoyl-ACP desaturase corresponding to the nucleotides 70 to 1245 in SEQ ID NO: 1, or any soybean nucleic acid fragment substantially homologous therewith encoding a functional stearoyl-ACP desaturase with the exception of a nucleic acid fragment having the sequence disclosed in Figure 2 of WO 91/13972."

"*3. A chimeric gene capable of transforming a soybean plant cell comprising a nucleic acid fragment, which comprises a nucleotide sequence encoding the soybean seed stearoyl-ACP desaturase corresponding to the nucleotides 70 to 1245 in SEQ ID NO:1 or any soybean nucleic acid fragment substantially homologous*

therewith encoding a functional stearoyl-ACP desaturase operably linked to suitable regulatory sequences producing antisense inhibition of soybean stearoyl-ACP desaturase in the seed."

"4. A chimeric gene capable of transforming a plant cell of an oil-producing species comprising a nucleic acid fragment of Claim 1 operably linked to suitable regulatory sequences resulting in overexpression of said soybean seed stearoyl-ACP desaturase in the plastid of said plant cell."

"5. A chimeric gene capable of transforming a plant cell of an oil-producing species comprising a nucleic acid fragment of Claim 2 operably linked to suitable regulatory sequences resulting in the expression of said mature soybean seed stearoyl-ACP desaturase enzyme in the cytoplasm of said plant cell."

"7. A method of producing oils from plant seed containing lower-than-normal levels of stearic acid comprising:
(a) transforming a plant cell of an oil producing species with a chimeric gene of Claims 4 or 5, (b) growing sexually mature plants from said transformed plant cells of an oil producing species;
(c) screening progeny seeds from said fertile plants for the desired levels of stearic acid; and
(d) crushing said progeny seed to obtain said oil containing lower-than-normal levels of stearic acid."

IX. The **auxiliary request 1** corresponded to the auxiliary request of the contested decision on the basis of which the opposition division maintained the patent. Claim 1 of this request was as claim 1 of the main request except for the disclaimer that read as follows:

"... with the proviso that said substantially homologous fragment is not a nucleic acid fragment having the sequence disclosed in Figure 2 of WO 91/13972 or a sequence with at least 60% homology thereto."

X. Claim 1 of **auxiliary request 2** read as claim 1 of auxiliary request 1 except for the introduction of the sentence "*which occurs naturally in a plant*" at the end of the disclaimer.

XI. Claims 1 and 7 of **auxiliary request 3** read as follows:

"*1. An isolated nucleic acid fragment comprising a nucleotide sequence encoding the soybean seed stearoyl-ACP desaturase corresponding to the nucleotides 70 to 1245 in SEQ ID No: 1, or a fragment thereof encoding a functional stearoyl-ACP desaturase."*

"*7. A method of producing oils from plant seed containing lower-than-normal levels of stearic acid comprising:*
(a) transforming a plant cell of an oil producing species with a chimeric gene capable of transforming a plant cell of an oil-producing species comprising a nucleic acid fragment which comprises a nucleotide sequence encoding the soybean seed stearoyl-ACP desaturase corresponding to the nucleotides 70 to 1245

in SEQ ID NO:1, or any soybean nucleic acid fragment substantially homologous therewith encoding a functional stearoyl-ACP desaturase, operably linked to suitable regulatory sequences resulting in overexpression of said soybean seed stearoyl-ACP desaturase in the plastid of said plant cell;
(b) growing sexually mature plants from said transformed plant cells of an oil producing species;
(c) screening progeny seeds from said fertile plants for the desired levels of stearic acid; and
(d) crushing said progeny seed to obtain said oil containing lower-than-normal levels of stearic acid."

Claim 3 of this request read as claim 3 of the main request (cf. Section VIII *supra*).

XII. The following documents are referred to in this decision:

D1: WO 91/13972 (publication date: 19 September 1991, claiming priority from *inter alia* D2);

D2: US 494,106 (filing date 16 March 1990);

D6: US 529,049 (filing date 25 May 1990, priority document of the patent-in-suit);

D8: A.R. van der Krol et al., Gene, 10 December 1988, Vol. 72(1-2), pages 45 to 50.

XIII. The arguments of appellant I (patentee) may be summarised as follows :

Main request and auxiliary requests 1 and 2
Article 123(2)(3) and 84 EPC

The application as filed referred to nucleic acid sequences encoding both the precursor and the mature stearoyl-ACP desaturase (SAD) from soybean seed. Homologous related sequences were defined by reference to nucleic acid hybridization and to changes in DNA codons resulting in amino acid substitutions. Claim 1 of these requests only incorporated the subject-matter of granted claim 2, i.e. the nucleic acid fragments encoding SAD as defined in granted claim 2.

Article 54(3)(4) EPC

The substantially homologous soybean nucleic acid fragments of claim 1 were not to be taken in isolation to encompass nucleic acid sequences which were not derived from soybean, such as the (76% homologous) safflower SAD sequence of document D1. These homologous fragments defined only the variations found in the sequences derived from soybean, such as the minor soybean SAD gene - disclosed in the patent in suit - with a 90% homology to the predominantly expressed SAD gene of SEQ ID NO: 1.

For assessing novelty, it was necessary to establish the subject-matter directly derivable from document D1 and entitled to the priority right from document D2. Document D2, insofar as it supported document D1, disclosed a single nucleic acid sequence encoding the safflower SAD enzyme (Figure 2) but it did not provide instructions for identifying other sequences. The homologous sequences having more than 60% homology to

the sequence of Figure 2 were only hypothetical since none of these sequences were actually isolated and methods for their isolation were not described in document D2.

Several choices had to be made, such as the specific method to use (protein purification, isolation with antibodies, hybridization with probes), the plants to screen, etc. If hybridization was chosen, then further choices were still required, such as the (short, long) probe for which no consensus SAD sequences were known, the (embryo, immature seeds, genomic) library, conditions of hybridization, which were different depending on the probe used, degree of homology, etc. Under the conditions used in document D2, the sole (DSAT-50) probe disclosed did not isolate the soybean SAD sequence nor the sequences from *Brassica campestris* or from *Ricinus communis*. This probe was of limited utility and in the absence of any information on consensus SAD sequences, the skilled person was not provided with the information necessary to isolate these homologous SAD sequences. The same deficiencies were evident when following the suggestion to use antibodies.

In fact, the skilled person was left alone, without sufficient information, to decide amongst unsatisfactory suggestions. There was no indication which would have allowed the identification - among the enormous number of theoretically possible sequences – of a subgroup of sequences containing the relevant soybean SAD sequences. These sequences were not disclosed and, even if they were to be considered as formally disclosed, they were not enabled. Therefore,

the disclaimer of the main request was sufficient to exclude the actual disclosure of document D1 and to restore the novelty of claim 1 of the main request.

Interpretations on what portions of the sequence in Figure 2 of document D1 were important could only be made under inventive step but not under considerations on novelty, since these portions were not directly derivable from this document. Figure 2 did not disclose a coding DNA sequence as a discrete fragment. Instead, this coding DNA sequence was embedded within the complete safflower cDNA sequence. In document D1, the homologous sequences were always defined in relation to the known SAD sequence. However, the only SAD sequence known was the one of Figure 2. All the references to the homology were made in comparison to the complete nucleic acid sequence of Figure 2. The disclaimer of auxiliary requests 1 and 2 excluded these homologous SAD sequences but not the soybean SAD sequence, since this soybean SAD sequence had a lower degree of homology to the complete nucleic acid sequence of Figure 2. Thus, the disclaimer as formulated in auxiliary requests 1 and 2 was complete and clear and restored the novelty of claim 1.

Auxiliary request 3
Admissibility

This request was a direct reaction to the findings of the Board that none of the disclaimers present in all the previous requests were allowable.

Articles 123(2)(3) and 84 EPC

Although linked to regulatory sequences, a reference to general nucleic acid fragments encoding functional SAD fragments was explicitly found in the application as filed. A generalisation of these fragments was also implicitly understood from the application as a whole.

Articles 54(3)(4) EPC

Document D1 referred to antisense inhibition in the context of sequences complementary to the specific safflower SAD sequence of Figure 2 or slightly truncated forms thereof. There was no disclosure of soybean SAD sequences nor of sequences substantially homologous therewith. Thus, there was no indication for selecting small fragments with high homology to soybean SAD sequences for producing antisense inhibition. With regard to longer sequences, there was no evidence that a sequence with only a 76% homology was sufficient to achieve antisense inhibition. In the absence of this evidence, the patentee was to be given the benefit of doubt. The methods of claims 7 and 8 comprised features that were not disclosed in document D1, such as the growth of sexually mature plants, screening of seeds, production of oil by crushing the seeds, etc.

XIV. The arguments of appellant II (opponent) may be summarized as follows:

Main request and auxiliary requests 1 and 2
Articles 123(2)(3) and 84 EPC

Claim 1 of the main request and auxiliary requests 1 and 2 referred to a stretch of nucleotides (70-1245 of SEQ ID NO:1) that was shorter than the one specified in claim 1 as granted (1-2243 of SEQ ID NO: 1). There were less restrictions on the nucleic acid sequence of claim 1 of these requests, since more freedom was left for possible variations in the nucleotides corresponding to 1-69 and 1245-2243 of SEQ ID NO: 1. By its dependency on claim 1, these variations were not contemplated in the fragment of claim 2 as granted. The requirement of "substantially homologous" was found – in the patent in suit and in the application as filed - associated to the complete sequence 1-2243 in SEQ ID NO: 1 and not to fragments thereof. Thus, claim 1 of these requests was broader than claim 1 as granted. The same objection applied for claims 3 and 12 of these requests.

Claim 11 of the main request and auxiliary requests 1 and 2 referred to the fragment of claim 2 as being linked (in a any possible manner) to suitable regulatory sequences, whereas in the corresponding granted claim 12 – by its dependency on granted claim 6 – this fragment was required to be operably linked to regulatory sequences.

Article 54(3)(4) EPC

Claim 1 of the main request and auxiliary requests 1 and 2 referred to soybean nucleic acid fragments substantially homologous to nucleotides 70-1245 in SEQ ID NO: 1 and encoding a functional SAD enzyme. Since

the reference to soybean was meaningless, any substantially homologous nucleic acid encoding a functional SAD enzyme fell within the scope of claim 1, independently of its actual origin. Figure 2 of document D1 disclosed the cDNA sequence of the safflower SAD enzyme. The coding region of this enzyme had an identity of 76% with the corresponding soybean SAD sequence in SEQ ID NO: 1. However, document D1 went far beyond this specific sequence, since it referred to other sequences that showed at least about 60% homology to the known desaturase sequence, i.e. to the safflower SAD sequence disclosed in Figure 2.

When assessing the teachings of document D1 and deciding on the priority right from document D2, the same standard had to be applied as when considering the disclosure of the patent in suit and its priority document D6, particularly, as regards the meaning of "substantially homologous" and its enablement. Document D1 validly claimed priority from document D2 not only for the specific safflower SAD sequence but for homologous sequences having at least 60% homology as well. The specific (DSAT-50) probe cited in document D2 was used for obtaining the complete cDNA sequence encoding the safflower SAD enzyme. However, once known, this complete sequence could be used for isolating other related sequences. Appropriate hybridization conditions could be easily found by the skilled person. Thus, the disclaimer of the main request was not sufficient since it did not exclude the complete disclosure of document D1.

The reference in document D1 to the degree of homology was a reference to both the coding DNA sequence and the complete cDNA sequence of Figure 2. The legend of the figure made it clear that Figure 2 provided a cDNA sequence (SEQ ID No.: 12) and the corresponding peptide sequence (SEQ ID No.: 13). However, the purpose of document D1 was to provide a method of producing a plant SAD enzyme in a host cell by expression from a nucleic acid sequence encoding the SAD enzyme. References were found in the description to the coding sequence, codons substitutions and modifications in this region, etc. Thus, it was evident to the skilled person that the coding region was the one of most interest. Therefore, homologous sequences would be understood as relating to the coding sequence of Figure 2. Since the coding sequence of Figure 2 had an identity of 76% with the corresponding sequence in the patent in suit (SEQ ID NO: 1), the disclaimer of auxiliary requests 1 and 2 was not sufficient to establish novelty.

Auxiliary request 3
Admissibility

The method of claim 7 relied on a chimeric gene comprising a nucleic acid fragment which, in all previous requests, had always been limited by a disclaimer. Claim 7 of auxiliary request 3 did not contemplate any limitation and reverted to the broader wording of the corresponding granted claim. This broadening was not admissible at this late stage of the proceedings.

Article 123(2) EPC

General functional SAD fragments of the nucleic acid fragment of claim 1 were not specifically disclosed as such in the application as filed. The reference indicated in this application required the SAD fragments to be linked to suitable regulatory sequences and therefore, it was not sufficient for the generalisation found in claim 1 of auxiliary request 3.

Article 54(3)(4) EPC

Document D8 stated that antisense inhibition was achieved by sequences having 80% homology to the target sequence. Thus, the safflower SAD sequence of document D1 with 76% homology to the soybean SAD sequence could be used to repress the expression of the soybean SAD gene. Although no experiments were conducted, this inhibition was likely to happen. Moreover, document D1 was not limited to antisense inhibition by the specific use of the safflower SAD sequence only but it comprised the use for antisense inhibition of other homologous sequences, in particular the ones with at least 60% homology. Thus, according to the appropriate standard of proof, claim 3 lacked novelty over document D1.

The method of claim 7 comprised the use of a nucleic acid fragment encoding a functional SAD enzyme and being substantially homologous with the soybean SAD sequence of the patent in suit. This definition comprised the safflower SAD sequence disclosed in document D1. All the specific steps cited in claim 7 were found in document D1 too, in particular, transformation of plant cells, culture of transformed

plant cells in appropriate selective medium, regeneration of plants, growing plants to seed and using of seeds to establish repetitive generations and to isolate vegetable oil compositions. Example 10 showed the screening and claim 18 referred to a method of modifying fatty acid composition in a plant. Thus, document D1 anticipated claim 7 of this auxiliary request 3 too.

XV. Appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of in that order: the main request filed on 29 January 2001 with the statement of grounds of appeal; or auxiliary request 2 filed on 22 September 2004; or auxiliary request 1 filed on 5 June 2000; or auxiliary request 3 filed at the oral proceedings on 22 October 2004.

XVI. Appellant II (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Main request
Articles 123(2)(3) EPC

1. Claim 1 as granted related to an isolated nucleic acid fragment comprising a nucleotide sequence encoding the soybean seed SAD corresponding to nucleotides 1-2243 in SEQ ID NO: 1, or any soybean nucleic acid fragment substantially homologous therewith encoding a functional SAD enzyme. Claim 2 as granted related to

the nucleic acid fragment of claim 1, wherein the nucleotide sequence encodes the soybean seed SAD precursor corresponding to nucleotides 70-1245 in SEQ ID NO: 1, or any soybean nucleic acid fragment substantially homologous therewith encoding a functional SAD precursor.

2. Claim 1 of the main request at issue (cf. Section VIII *supra*) corresponds to claim 2 as granted. Appellant II sees in this amendment an extension of the protection granted because in its view the sequence of nucleotides 70-1245 now claimed is no longer under the constraints of the sequence of nucleotides 1-2243 to which it previously referred. Thereby, in its view, unlimited variations are allowed in the regions 5' upstream and 3' downstream, whilst before these regions necessarily comprised the nucleotides 1-69 and 1246-2243 respectively of SEQ ID NO: 1 (cf. Section XIV *supra*).

3. The Board cannot follow appellant's II view for the reason that claim 2 as granted is understood as further defining the generic fragment referred to in claim 1, i.e. one of the many possible soybean nucleic acid fragments substantially homologous with the sequence of nucleotides 1-2243 of SEQ ID NO: 1. Since in granted claim 1 the homology is not required to be uniformly distributed along the complete sequence of the isolated nucleic acid fragment and, according to the description "*substantially homologous refers to nucleic acid molecules which require less stringent conditions of hybridization than those for homologous sequences*" (cf. page 6, lines 27 to 29) but no particular hybridization conditions are specified, no structural limitations can be associated to regions 5' upstream and 3' downstream

of the fragment defined in claim 2. This fragment does not need to be homologous to the nucleotides 1-69 and 1246-2243 in SEQ ID NO: 1. Thus, claim 1 of the main request represents no extension of the protection conferred (Article 123(3) EPC).

4. References to a fragment corresponding to nucleotides 70-1245 in SEQ ID NO: 1 are also found in the application as filed (see *inter alia* claim 2 as filed). Claim 1 of the main request fulfils the requirements of Articles 123(2) EPC too.

5. As for claim 11, the omission of the term "*operably*" in connection with the feature "*linked to suitable regulatory sequences*" results in an offence against Article 123(3) EPC. During oral proceedings, appellant I offered to reinstate the term "*operably*" in order to overcome the objection. However, the amendment was not formally introduced in view of the outcome of the discussion on the allowability of the disclaimer (cf. points 6 to 19 *infra*).

Article 54(3)(4) EPC
The claimed subject-matter

6. Claim 1 comprises two different embodiments, a first one directed to an isolated nucleic acid fragment comprising a specific nucleotide sequence encoding the soybean seed SAD (nucleotides 70-1245 in SEQ ID NO:1) and a second embodiment comprising "*any soybean nucleic acid fragment substantially homologous therewith encoding a functional stearoyl-ACP desaturase*" (cf. Section VIII *supra*). Whereas there is no prior art on file disclosing the nucleotide sequence of the first

embodiment, the question arises whether, and to which extent, the second embodiment is anticipated by document D1 cited under Article 54(3)(4) EPC.

7. This second embodiment refers to a "*soybean nucleic acid fragment*", wherein "*soybean*" indicates the origin of the nucleic acid and thus, relates to the process of production. It is established case law of the Boards of Appeal that, for the purposes of patentability, such process features are to be considered if evidence is provided that the process confers distinct differences in the properties of the product and the skilled person is made aware of these differences so that it can always recognize the claimed product and discard any product not having them (cf. "Case Law of the Boards of Appeal of the European patent Office", 4th edition 2001, I.C.3.2.7, page 72 and *inter alia* T 522/99 of 18 May 2004, point 1 of the Reasons). In the present case, a nucleic acid derived from soybean does not have any distinct feature that allows the skilled person to recognize it as being derived from soybean. In the absence of such a feature, the second embodiment covers any nucleic acid fragment *"substantially homologous*" with nucleotides 70-1245 in SEQ ID NO: 1 encoding a functional SAD enzyme.

8. For interpreting the correct meaning of "*substantially homologous"*, the description of the patent in suit is taken into consideration. Page 6, lines 22 to 31 defines "*substantially homologous*" as "*nucleic acid molecules which require less stringent conditions of hybridization than those for homologous sequences*". However, there is no degree of homology indicated nor any conditions of hybridization. In view of this

definition, the second embodiment of claim 1 is considered to embrace any nucleic acid fragment encoding a functional SAD enzyme and hybridizing - under any possible hybridization conditions - to the sequence 70-1245 in SEQ ID NO: 1, no matter how high or low the degree of homology might actually be.

9. It is in the light of this interpretation that claim 1 comprises subject-matter anticipated by document D1 and, for this reason, a disclaimer is required to restore novelty. In line with the requirements established in the decision G 1/03 (cf. *supra*, point 3 of the Reasons), the only justification for the disclaimer is to exclude a novelty-destroying disclosure and the disclaimer should therefore be accordingly formulated. Thus, in order to assess the correct extent of the disclaimer, the disclosure of document D1 must be analyzed in detail.

The prior art document D1

10. Document D1 discloses the **specific** nucleic acid sequence encoding the safflower SAD enzyme. Figure 2 provides a specific cDNA sequence (SEQ ID NO: 12) and the corresponding peptide sequence (SEQ ID NO: 13) derived from safflower, including the sequences encoding the plastid transit peptide and the mature SAD protein (cf. page 4, lines 33 to 37 and Figure 2).

11. An **intermediate generalization** is contemplated by explicit reference to homologous nucleic acid sequences which are defined as showing "*at least about 60% homology, and more preferably at least 70% homology, between the known desaturase sequence and the desired*

plant desaturase of interest" (cf. page 16, lines 26 to 28 and page 17, lines 16 to 20).

12. Document D1 further comprises a **broad generalization** based on the specific safflower SAD sequence as it refers to the use of the specific sequence in known methods for recovering DNA sequences encoding other plant desaturases (cf. page 6, lines 30 to 35). In particular, SAD probes, up to the full length of the gene encoding the SAD polypeptide, long (>100 bp) nucleic acid fragments, etc. (cf. page 17, lines 28 to page 18, line 2) as well as general (polyclonal and monoclonal) antibodies (cf. page 17, lines 6 to 15) are mentioned as being useful for isolating plant SAD of developing seed obtained from other oilseed plants, such as soybean, coconut, oilseed rape, etc. (cf. page 18, line 33 to page 19, line 3 and claim 1). Once the desired plant SAD sequence is obtained, it might be manipulated in a variety of ways, including the synthesis of all or part of the SAD sequence (cf. page 13, lines 8 to 21).

Priority rights of document D1 from document D2

13. There is no doubt and, it has not been contested, that the specific safflower SAD sequences of document D1 enjoy the priority right from document D2 (cf. page 4, lines 3 to 8 and Figure 2) which chronologically precedes document D6, the priority document of the patent in suit. There is also formal support for the intermediate (cf. page 11, lines 4 to 17) and the broader generalization (cf. page 7, line 27 to page 8, line 4, page 11, line 19 to page 12, line 2, page 12,

line 24 to page 13, line 7, page 13, lines 8 to 21 and claims 1, 27 to 29).

14. It has been argued by appellant I, however, that none of these two generalizations is entitled to the priority right since the actual teaching in document D2 for these generalizations is so general that the document is in fact not enabling. In particular, reference has been made to the deficiencies and problems associated with the design of suitable probes, the absence of information for determining the consensus regions, the lack of disclosure of appropriate hybridization conditions, etc. (cf. Section XIII *supra*).

15. However, once a nucleic acid sequence encoding the safflower SAD – the complete nucleotide sequence and selected restriction enzyme sites (Figures 2 and 4 of document D2) - is made available to the skilled person, the isolation of homologous nucleic acid sequences encoding other plant SAD enzymes as indicated in document D2 does not involve anything out of the ordinary. Neither the selection of suitable probes – complete cDNA sequence or long (restriction) fragments (>100bp) – nor the selection of (high, low stringent) hybridization conditions require any particular skill, especially when no specific degree of homology - or a very low (60%) one - is desired. In fact, the patent in suit itself presumes that the skilled person will have this level of skill and will not require more information in working in the generalized area claimed. The same standard must be applied to this substantially contemporaneous prior art (cf. *inter alia* T 1070/00 of 23 October 2003, points 9.4 and 9.5 of the Reasons and

T 1099/99 of 4 December 2002, point 3.3. of the Reasons).

16. At the level of the intermediate and broad generalization of the specific safflower SAD sequence of Figure 2, there is identity of subject-matter between documents D1 and D2 in the sense of G 2/98 (OJ EPO 2001, 413, point 9 of the Reasons). Thus, the specific safflower SAD sequence as well as the intermediate and broad generalizations of document D1 are entitled to the priority right from document D2.

Claimed subject-matter versus prior art document D1

17. As stated above (cf. point 8 *supra*), claim 1 of the main request embraces any nucleic acid fragment "*substantially homologous*" with the nucleotides 70-1245 in SEQ ID NO: 1 and encoding a functional SAD enzyme. The safflower SAD sequence of document D1 has an identity of 76% at the nucleotide level with the corresponding coding sequence of the soybean seed SAD (SEQ ID NO: 1) and thus, it falls within claim 1. The disclaimer in claim 1, however, excludes this specific safflower SAD sequence.

18. Nevertheless, the disclaimer does not exclude the complete disclosure of document D1. Neither the intermediate (related nucleic acid sequences with at least about 60% homology, more preferably at least about 70% homology) nor the broad generalization of document D1 are excluded from claim 1, which covers these SAD sequences by reference to "*substantially homologous*" nucleic acid fragments (cf. point 8 *supra*).

19. Thus, the disclaimer is incomplete and it cannot restore the novelty of claim 1 over document D1. Consequently, the main request cannot be allowed under Article 54(3)(4) EPC.

Auxiliary requests 1 and 2
Articles 123(2)(3) and 84 EPC

20. The sentences "*or a sequence with at least 60% homology thereto"* and "*or a sequence with at least 60% homology thereto which occurs naturally in a plant*" in the disclaimers in claim 1 of auxiliary requests 1 and 2 respectively (cf. Sections IX and X *supra*), were introduced in an attempt to complete the disclaimers in view of the disclosure of document D1. They do not raise further issues under Article 123 EPC other than the ones referred to for the main request (cf. points 1 to 5 *supra*).

21. The reference to sequences which "*occur naturally in a plant*" in auxiliary request 2 raises issues of clarity under Article 84 EPC. However, in view of the deficiencies of the disclaimers and the conclusions drawn therefrom for both auxiliary requests 1 and 2 (cf. point 22 *infra*), the Board does not see any need to examine these issues.

Article 54(3)(4) EPC

22. The disclaimers of these auxiliary requests do not exclude the broader generalization which can be derived from document D1 and which is also entitled to the priority of document D2 (cf. points 12 to 16 *supra*). The substantially homologous nucleic acid fragments of

claim 1 (cf. point 8 *supra*) and this broad generalization overlap to a large extent, namely for all nucleic acid sequences encoding a functional SAD enzyme and hybridizing - under any possible conditions – to both the nucleic acid sequence encoding the soybean SAD enzyme of the patent in suit and to the nucleic acid sequence encoding the safflower SAD enzyme of document D1.

23. Therefore, auxiliary requests 1 and 2 do not fulfil the requirements of Articles 54(3)(4) EPC.

Auxiliary request 3
Admissibility

24. In the present case both the patent proprietor and the opponent have appealed. Thus, the principle of *reformatio in peius* referred to in decision G 4/93 (OJ EPO 1994, 875) is not applicable in the present case.

25. A question does however arise in the present case in connection with claim 7 of auxiliary request 3 (cf. Section XI *supra*), which while not extending in scope beyond the claims as granted and not adding subject matter beyond that of the application as originally filed, thus meeting the requirements of Article 123(2) and (3) EPC, is of broader scope than claim 7 of the main request put forward before the opposition division and on appeal. This broadening arises because this claim 7 was dependent on claim 4 or 5, which were in turn dependent on claim 1 which contained an exclusion by way of disclaimer "*of a nucleic acid fragment having the sequence disclosed in Figure 2 of WO 91/13972*" (cf. Section VIII *supra*). This was a disclaimer which was

based solely on document D1, prior art only for the purpose of Article 54(3) EPC. This disclaimer was not necessary to establish novelty of claim 7 over document D1, because such existed anyway as features (c) and (d) are not mentioned either explicitly or implicitly in document D1. The steps required by these features might be obvious ones to a reader of document D1, but according to established case law, such an obvious nature is not enough for document D1 to destroy novelty (cf. point 34 *infra*). As the disclaimer is not necessary to establish novelty and it does not have a basis in the application as originally filed, it is not allowable under Article 123(2) EPC, for the reasons set out in the recent decision G 1/03 (*supra*). The omission of the disclaimer by appellant I meets the requirements of Rule 57a EPC, as it removes an objection to the claim.

26. The only question thus is whether appellant I can be allowed to put forward a claim which in this respect is broader than the one he asked for before the Opposition Division or in the grounds of appeal, or whether this should be refused as an abuse of procedure. The Board considers by analogy to the situation considered by the Enlarged Board of Appeal in point 15 of its decision G 1/99 (OJ EPO 2001, 381) that if the amendment originally sought by the patentee is not allowable and is not necessary for validity of the claim, and the claim is within the limits of Article 123(3) EPC, then the only appropriate course is to allow the appellant patentee to omit the disclaimer. If there is a case for allowing such a change to validate a claim even in the case of a patentee who is solely a respondent, then

there is all the more reason to allow it where the patentee has himself appealed.

Articles 123(2)(3) and 84 EPC

27. As for claim 1 of the main request (cf. points 1 to 3 *supra*), no extension of protection is seen in a limitation to the specific soybean seed SAD corresponding to nucleotides 70-1245 in SEQ ID NO: 1 and functional fragments thereof. Nucleic acid fragments encoding a functional SAD enzyme and having an homology of 100% with the corresponding sequence in SEQ ID NO: 1 are comprised within the substantially homologous sequences of the claims as filed. Therefore, a formal basis is found in claim 2 of the application as filed too. Although linked to suitable regulatory regions, generic fragments are identified and referred to on page 9, line 35 to page 11 line 1 of the application as published.

28. The limitation of the subject-matter of claim 1 results in amendments to other claims, some of them being dependent on amended claim 1 and others referring to the original broader isolated nucleic acid fragments. No clarity problems are introduced in doing so and the objection raised for claim 11 of the main request, now claim 12 in the request under consideration (cf. point 5 *supra*), has been overcome.

29. Thus, the third request fulfils the requirements of Articles 123(2)(3) and 84 EPC.

Article 54(3)(4) EPC

30. As stated in point 6 *supra*, there is no prior art on file disclosing the specific nucleotide sequence encoding the soybean seed SAD enzyme and corresponding to the nucleotides 70-1245 in SEQ ID NO: 1 or functional fragments thereof. Thus, claim 1 of this request and claims directly dependent thereon meet the conditions of Article 54(3)(4) EPC.

31. Claim 3 relates to a chimeric gene comprising a nucleic acid fragment with the specific sequence of claim 1 or "*any soybean nucleic acid fragment substantially homologous therewith*" in the broad sense discussed in point 8 *supra*. However, claim 3 explicitly requires that these fragments (operably linked to suitable regulatory sequences) produce antisense inhibition of the soybean seed SAD in the seed (cf. Section XI *supra*), i.e. they inhibit by antisense – based on base pair homology and binding - the specific sequence of soybean seed SAD, which is understood to have the predominant sequence of SEQ ID NO: 1 or the SAD gene with 91% identity to SEQ ID NO: 1 (cf. page 8, line 44 to page 9, line 1 of the patent in suit). Thus, the chimeric gene of claim 3 must comprise a specific antisense sequence capable of producing the required inhibition.

32. Although it has been argued that sequences with 80% homology, or even sequences with lower homology, might already produce such inhibition (cf. page 47, right-hand column, first full paragraph, document D8), proper conditions and reasonable selected fragments might strongly influence the ultimate outcome (cf. page 47, left-hand column, first full paragraph,

document D8). There is no evidence on file showing that an antisense sequence of the (complete) sequence encoding the safflower SAD enzyme of document D1 may actually inhibit the sequence encoding the soybean SAD enzyme of the patent in suit - both sequences being only 76% homologous. Similar deficiencies are found for the antisense SAD sequence from *B. campestris* of example 13, which is not even entitled to the priority.

33. Moreover, there is no suggestion in document D1 to specifically select an appropriate group of antisense sequences (capable of inhibiting the specific soybean SAD enzyme) from the particular sequences disclosed therein (even less for suitable fragments thereof), since only references to generic SAD sequences are found when discussing the antisense constructs (cf. *inter alia* page 8, lines 5 to 12 and page 14, lines 11 to 23 in document D1). Thus, the purposive selection of specific antisense SAD sequences found in claim 3 - capable of inhibiting the specific soybean SAD enzyme - is not anticipated in document D1.

34. The method of claim 7 comprises the transformation of a plant cell with a chimeric gene comprising any soybean nucleic acid fragment encoding a functional SAD and being "*substantially homologous*" with nucleotides 70-1245 in SEQ ID NO: 1. However, the method further comprises the overexpression of the SAD enzyme in the plastid (or in the cytoplasm in claim 8) of the plant cell and, as additional steps, the screening of progeny seeds from fertile plants for the desired levels of stearic acid (step c) and crushing of said progeny seed to obtain the oil containing lower-than-normal levels of stearic acid (step d). None of these features nor

the additional steps or their specific combination is disclosed in document D1 (cf. page 24, lines 11 to 26 and claims 18 to 22). In Example 10 thereof, the screening is carried out in regenerated green rooted shoots using an antibiotic marker (NPT II activity) and with no reference to the desired levels of stearic acid. Claim 18 of document D1 refers to a method of modifying fatty acid composition in a plant host cell but it is silent on the subcellular location of expression, on the regeneration of sexually mature plants, on the screening of the progeny seeds or the method used (crushing) for obtaining the plant oil.

35. The appellant II raised no further objections under Article 54(3)(4) EPC against the subject-matter of this request, in the light of the prior art on file. Nor does the Board have any further objections against this request. Thus, the requirements of Article 54(3)(4) EPC are fulfilled.

Order

For these reasons it is decided that:

1. The decision is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the claims of auxiliary request 3 filed at the oral proceedings on 22 October 2004 and a description to be adapted thereto.

The Registrar: The Chairman:

A. Wolinksi L. Galligani