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**Datasheet for the decision
of 10 September 2007**

Case Number: T 0542/04 - 3.3.04

Application Number: 92922535.7

Publication Number: 0608359

IPC: A01H 5/10

Language of the proceedings: EN

Title of invention:

Soybean products with improved carbohydrate composition and soybean plants

Patentee:

E.I. DU PONT DE NEMOURS AND COMPANY

Opponent:

Archer-Daniels-Midland Company

Headword:

Soybean products/E.I. DU PONT DE NEMOURS

Relevant legal provisions (EPC 1973):

EPC Art. 54, 56, 83, 123(2), (3)
EPC R. 88

Relevant legal provisions:

-

Keyword:

"Main request - added matter, extension of scope of protection (no) - sufficiency, novelty, inventive step (yes)"

Decisions cited:

T 0019/90, T 0020/94, T 0727/95, T 0354/97

Catchword:

-



Case Number: T 0542/04 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 10 September 2007

Appellant: Archer-Daniels-Midland Company
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
18 February 2004 concerning maintenance of
European patent No. 0608359 in amended form.

Composition of the Board:

Chair: U. Kinkeldey
Members: B. Claes
R. Moufang

Summary of Facts and Submissions

1. The appeal of the opponent (the appellant) lies from the interlocutory decision of the opposition division according to which the patent EP-B-0 608 359, with the title "Soybean products with improved carbohydrate composition and soybean plants", could be maintained in amended form (Article 102(3) EPC) on the basis of a main request.

- II. The patent had been opposed in its entirety on the grounds for opposition in Articles 100(a) EPC, combined with Articles 52(2) (a), 54 and 56 EPC as well as Articles 100(b) and 100(c) EPC.

- III. With a communication dated 17 April 2007 the board issued summons to attend oral proceedings.

- IV. With a letter dated 30 July 2007 the appellant's representative informed the board that the appellant would not attend the oral proceedings.

- V. Oral proceedings were held as scheduled on 10 September 2007 in the absence of the appellant. During the oral proceedings the respondent (patent proprietor) filed a new main request. The claims of this request were:

"1. Soybeans with a genotype that confers a heritable phenotype of seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed), said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding, wherein said soybeans are obtainable from progeny lines prepared by a method comprising:

(a) crossing a soybean plant comprising a *stc1x* allele, wherein said plant is of a line that has a genotype at the *Stc1* locus that confers a phenotype of a seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed), with an agronomically elite soybean parent which does not comprise said allele, to yield a F1 hybrid;

(b) selfing the F1 hybrid for at least one generation; and

(c) identifying the progeny of step (b) homozygous for the *stc1x* gene and capable of producing seed having a stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed)."

This claim 1 is identical to claim 1 of the main request before the opposition division, but for two clerical corrections.

"2. Soybeans of claim 1 wherein said stachyose content of said soybeans is less than **15 $\mu\text{mol/g}$** (based on undried seed)." (emphasis added by the board)

This claim 2 is identical to claim 2 before the opposition division, but for the amendment of 19 $\mu\text{mol/g}$ to now 15 $\mu\text{mol/g}$.

Claims 3 to 4 are dependent claims and are identical to claims 3 to 4 of the main request before the opposition division.

"5. Method of using soybeans of any one of claims 1 to 4, the method comprising further processing said soybeans to obtain a desired soy product by means known *per se*."

"6. Method of making a soy protein product comprising processing soybeans of any one of claims 1 to 4 by means known *per se*."

Claims 5 and 6 are identical to claims 5 and 6 of the main request before the opposition division.

"7. A method of making a full fat soy protein product comprising:

- (a) removing the meats from the hulls of cracked soybeans as defined in any one of claims 1 to 4;
- (b) flaking the meats obtained in step (a) to obtain a desired flake thickness;
- (c) heat-denaturing the flakes obtained in step (b) to obtain a desired Nitrogen Solubility Index; and
- (d) grinding the denatured flakes of step (c) to obtain a desired particle size."

"8. A method of making a defatted soy protein product comprising:

- (a) removing the meats from the hulls of cracked soybeans as defined in any one of claims 1 to 4;
- (b) flaking the meats obtained in step (a) to obtain a desired flake thickness;
- (c) contacting the full fat flakes obtained in step (b) with a solvent to extract oil from the flakes to a desired content level;
- (d) heat-denaturing the defatted flakes obtained in step (c) to obtain a desired nitrogen solubility; and
- (e) grinding the denatured, defatted flakes obtained in step (d) to obtain a desired particle size."

These claims 7 and 8 are identical to claims 7 and 8 before the opposition division, but for a clerical correction.

"9. A method of making a soy protein concentrate product comprising:

- (a) removing the meats from the hulls of cracked soybeans as defined in any one of claims 1 to 4;
- (b) flaking the meats obtained in step (a) to obtain a desired flake thickness;
- (c) contacting the full fat flakes obtained in step (b) with a first solvent to extract oil from the flakes to a desired oil content level;
- (d) contacting the defatted flakes obtained in step (c) with a second solvent to obtain a soy protein concentrate product with a protein content $(6.25 \times N)$ of not less than 65% (dry basis)."

Claim 9 and dependent claims 10 and 11 are identical to claims 9 to 11 of the main request before the opposition division.

"12. A method of making an isoelectric soy protein isolate product comprising:

- (a) removing the meats from the hulls of cracked soybeans as defined in any one of claims 1 to 4;
- (b) flaking the meats obtained in step (a) to obtain a desired flake thickness;
- (c) contacting the full fat flakes obtained in step (b) with a first solvent to extract oil from the flakes to a desired oil content level;
- (d) contacting the defatted flakes obtained in step (c) with an aqueous solution of pH 8 - pH 9;

(e) separating the soluble and insoluble fractions of the product of step (d) by physical means;
(f) adjusting the pH of the soluble fraction obtained in step (e) to obtain a protein precipitate;
(g) separating the protein precipitate of step (f) from the soluble fraction by physical means to obtain a soy protein isolate;
(h) washing the product of step (g); and
(i) spray-drying the washed product of step (h) to obtain an isoelectric soy protein isolate product."

Claim 12 and dependent claim 13 are identical to claims 12 and 13 of the main request before the opposition division.

"14. A soy protein product made from a soybean as defined in any one of claims 1 to 4 wherein said product is soy milk **having a stachyose content of less than 45 $\mu\text{mol/g}$ (as is)**." (emphasis added by the board)

"15. An undenatured, defatted soy protein product made from a soybean as defined in any one of claims 1 to 4 **having a stachyose content of less than 45 $\mu\text{mol/g}$ (as is)**." (emphasis added by the board)

"16. A heat-processed, desolventized and toasted soy protein product made from a soybean as defined in any one of claims 1 to 4 **having a stachyose content of less than 45 $\mu\text{mol/g}$ (as is)**; and having a true metabolizable energy content of greater than 2850 Kcal/kg (dry basis)." (emphasis added by the board)

17. A heat-processed, defatted, flash-desolventized soy protein product made from a soybean as defined in any

one of claims 1 to 4 **having a stachyose content of less than 45 $\mu\text{mol/g}$ (as is).**" (emphasis added by the board)

Claims 14 to 17 are identical to claims 14 to 17 of the main request before the opposition division, but for the added emphasised wording.

"18. A soy protein concentrate product having a protein content ($6.5 \times N$) of not less than 65% (dry basis) produced by the method comprising:

- (a) removing the meats from the hulls of cracked soybeans as defined in any one of claims 1 to 4;
- (b) flaking the meats obtained in step (a) to obtain a desired flake thickness;
- (c) contacting the full fat flakes obtained in step (b) with a first solvent to extract oil from the flakes to a desired content level;
- (d) contacting the defatted flakes obtained in step (c) with a second solvent to obtain a soy protein concentrate product with a protein content ($6.25 \times N$) of not less than 65% (dry basis)."

"19. A pet food product having a soybean inclusion rate of between 25 and 41% and a total stachyose content of less than $10 \mu\text{mol/g}$ (dry basis) wherein said soybean is as defined in any one of claims 1 to 4."

"20. A method for producing a soybean protein product with a reduced stachyose content comprising:

- (a) crossing an agronomically elite soybean line with the mutant soybean line LR28 or LR484 having a genotype that confers a heritable phenotype of seed stachyose content of less than $30 \mu\text{mol/g}$ (based on undried seed);

(b) screening the seed of progeny plants obtained from step (a) for a seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed); and
(c) processing the seed selected in step (b) to obtain the desired soybean protein product."

Claims 18 to 20 are identical to claims 18 to 20 of the main request before the opposition division.

"21. A method of using a soybean having a genotype at the *Stc1* locus that confers a phenotype of a seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed) to produce progeny lines, the method comprising:

(a) crossing a soybean plant comprising a *stc1x* allele with an agronomically elite soybean parent which does not comprise said allele, to yield a F1 hybrid;
(b) selfing the F1 hybrid for at least one generation;
and
(c) identifying the progeny of step (b) homozygous for the *stc1x* gene and capable of producing seed having a stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed)."

Claims 21 and dependent claim 22 are identical to claims 21 and 22 of the main request before the opposition division, but for clerical corrections.

"23. The method of claim 21 wherein progeny is identified which is capable of producing seed having a stachyose content of less than **15 $\mu\text{mol/g}$** (based on undried seed)." (emphasis added by the board)

This dependent claim 23 is identical to claim 23 of the main request before the opposition division, but for the amendment of 19 $\mu\text{mol/g}$ to now 15 $\mu\text{mol/g}$ and the deletion of the reference to claim 22.

VI. The following documents are cited in the present decision:

- (4): Saravitz (1986), PhD Thesis, North Carolina State University, Hort. Sci. Department.
- (6): Mustakas *et al.* (1962), J. American Oil Chemists' Soc., Vol. 39, p. 222-226.
- (11): "Soy Protein Products - Characteristics, Nutritional Aspects and Utilization" (1987), Handbook published by the Soy Protein Council, 1255 Twenty-Third Street, NW, Washington D.C..
- (14a): Manual on Mutation Breeding (1977) published by The International Atomic Energy Agency, p. 213-219.
- (18): Saravitz *et al.* (1987), Plant Physiol., Vol. 83, p. 185-189.
- (19): Hymowitz *et al.* (1972), Agronomy Journal, Vol. 64, p. 613 to 616.
- (20): Hymowitz & Collins (1974), Agronomy Journal, Vol. 66, p. 239 to 240.
- (26): US 3,943,266

(28): US 3,632,346

(29): Correspondence of April and May 1991 concerning requests of LR28 (PI 200.508) at the USDA Soybean Germplasm Collection by Pioneer Hi-Bred Int., Inc. and its shipment to the requester.

(31): Johnson (1983), "Utilization of Soybeans in the Western Hemisphere", in: Soybean Research in China and the United States, Eds.: Irwin et al., p. 95 to 98.

(32): US 4,645,677

(33): Rackis (1981), J. American Oil Chemists' Soc., Vol. 5, p. 503-509.

Annex 5: Experimental data submitted by the respondent with letter dated 17 January 2005 providing a comparison of the quality traits of non-fat soymilk powder of commodity soybeans and the low stachyose soybeans of the invention.

Annex 6: Experimental data submitted by the respondent with letter dated 17 January 2005 providing a comparison of the stachyose levels as measured in documents (4), (18), (19) and (20) as well as measurements of the same lines made in the patent and in previous submissions.

VII. The appellant's arguments insofar as relevant to the present decision may be summarised as follows:

Added matter

Claim 1; "said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding"

- The feature "said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding" in claim 1 extended beyond the content of the application as filed (Article 100(c) EPC). Firstly, the application considered "soybeans" that underwent mechanical processing no longer to be "soybeans" but rather "processed soy protein products". Secondly, there was no support in the application for the term "mechanical processing". In particular, "physical" processing was broader than "mechanical" and a generalisation from "dehulling", "grinding" and "cracking" was not allowed seeing that following *inter alia* decision T 354/97 of 3 May 2000, the case law denied that the disclosure of specific examples supported a generalisation in regard to the category to which the example belong.

Claims 5 to 9, 12, 14, 18 and 21; stachyose content of "less than 30 $\mu\text{mol/g}$ "

- The stachyose content of less than "30 $\mu\text{mol/g}$ ", included in claims 5 to 9, 12, 14 to 18 by their back-reference to claims 1 to 4 and explicitly in claim 21, was not directly and unambiguously derivable from the application. The only mention of this content in the application as filed was on page 7, line 32, i.e. in the context of seeds,

plant lines, plants and progeny and the application did not mention products made there from. The application defined the stachyose content of the soybeans in the claimed products and methods to be less than "45, 35 or 15 $\mu\text{mol/g}$ ".

Claim 20; "mutant line"

- The application as filed nowhere defined the soybean LR28 line as a "mutant line".

Sufficiency of disclosure

- Any claimed subject-matter going beyond the two specifically disclosed low stachyose soybean lines LR28 and LR484 and the exemplified genes *stc1a* and *stc1b* was not enabled. The patent either taught exhaustive screening of existing soybean lines or mutagenesis followed by screening the mutants whereby a skilled person would have to perform all steps as were necessary to make the invention, such as assaying the stachyose content, determining heritability of the trait involving performing crossing experiments, in view of the fact that claim 1 of the main request now requires the *stc1x* gene to be present, performing the allelism test and, in addition for the mutagenesis protocol, performing mutagenesis experiments. This constituted undue experimentation in the sense that the reproduction of the invention over the whole claimed breadth required the finding of a solution to the technical problem, required the performance of a research program, required the application of inventive skill, whereby the

teaching of the patent did not necessarily and directly lead towards the success and/or where the achievement of the intended result is a chance event.

- Decision T 727/95 (OJ EPO 2001, 1) dealt with a similar situation relating to the sufficiency of disclosure of biological material which was neither exemplified in the patent, nor derived from the exemplified material and should be followed. Based on the analogy with the case underlying this decision the board should find the patent to lack sufficient disclosure of the claimed subject-matter.

- Document (14a) indicated that mutagenesis as such was a matter of chance and that it was rarely possible to predict mutagenesis frequencies.

Novelty

- The subject-matter of claim 14 was not novel over conventional soy milk as was disclosed e.g. in documents (26) and (27), because the features characterising the soybeans of claims 1 to 4 were not carried through on the claimed protein product made there from. In particular it was not possible for a skilled person to determine for a given soy milk from which soybean the soy milk was made as stachyose content changed during the production process and the presence of a stc1x allele could not be determined due to the absence of any molecular characterisation of the stc1x allele. The milk as subject-matter of claim 14 could

therefore be made of any soybean. This point of view was supported by e.g. decision T 20/94 of 4 November 1998 where it was found that "made from" has no technically limiting effect.

- The subject-matter of claim 14 was also not novel, even if the 30 $\mu\text{mol/g}$ stachyose content limit of claim 1 applied to the soybean milk. Document (28) disclosed soy milk (see examples 2 and 6) wherein the stachyose was removed enzymatically.

- Similar arguments as to the subject-matter of claim 14 applied to claims 15, 17 and 18 in view of the disclosures in e.g. in document (11) (see table at page 3) and document (28) (e.g. at column 2, lines 1 to 7 and column 2, line 33 to column 5, line 67) for claim 15; in document (6) (page 222, "Materials and Methods, 1st sentence) for claim 17 and document (6) (page 222, "Materials and Methods, 1st sentence; page 225, 2nd column, last paragraph) and (11) (figure 1, page 4, page 5 "Soy Protein Concentrates") for claim 18, respectively.

Inventive step

- In view of closest prior art document (4), the technical problem in the context of claim 1, was to provide soybeans with a heritable stachyose content which was lower than that of the normally used soybean lines. Document (19) described several soybean lines having a seed low stachyose content and stated that "*[p]erhaps additional screening will reveal lines lower in stachyose*

than those found in this study, yet which are high in protein and oil" (page 615, last sentence). Similarly, document (20) reported on soybean lines having a seed stachyose content of less than 30 $\mu\text{mol/g}$ (page 240, table 3) and stated that certain soybean lines "*appear to be excellent genetic sources for low stachyose content*" (page 240, right hand column, lines 7 and 8). Hence, the skilled person was motivated to seek soybean lines with a heritable low stachyose phenotype and had every reason to expect that the technical problem could be solved by screening for such lines. The skilled person would therefore have followed exactly the same path as described in the patent and would therefore inevitably have identified LR28, i.e. a soybean line commonly used in breeding programs (see document (29)), and the genetic locus *Stc1* conferring the low stachyose phenotype.

- Claims 5 to 19 related to various methods for preparing soybean products by using the soybeans of claims 1 to 4. The use of soybeans in the claimed methods was however well-known in the art and belonged to the common general knowledge as could be taken from the disclosures in e.g. documents (6) to (8), (11) and (31).

- The provision of the subject-matter of claims 14 to 19 was obvious in view of prior art describing methods for reducing flatulence-causing sugars from leguminous protein material e.g. by the enzymatic removal of stachyose and raffinose from soy protein products (document (28)), the removal

of flatulence-causing sugars by ultrafiltration from beans (document (32)) or from soybean foodstuffs (document (33)).

- The subject-matter of claim 20 was not inventive seeing that the skilled person would have inevitable arrived at isolating soybean lines being homozygous for *stclx*, for which LR28 and LR484 were exemplary.

VIII. The respondent's arguments insofar as relevant to the present decision may be summarised as follows:

Added matter

Claim 1; "said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding"

- The application as filed, e.g. on page 3, lines 1 to 6, disclosed processing which starts by machinery which conduct inevitably "mechanical processing". In addition, mechanical processing rendered the soybeans non-viable.
- The application therefore taught clearly and unambiguously both mechanical processing of soybeans and the resultant characteristic of non-viability.
- The fact that allegedly the patent application as filed considered "soybeans" that had undergone mechanical processing no longer to be "soybeans"

but rather "processed soy protein products" was a matter of clarity.

Claims 5 to 9, 12, 14, 18 and 21; stachyose content of "less than 30 $\mu\text{mol/g}$ "

- It was clear that the invention aimed at making soybeans with low stachyose, which could be used to produce soybean products for consumption. The disclosure of the methods for plants and seeds on the one hand and of the processed products on the other hand could therefore not be seen separately. To read it differently would imply that the application only intended some beans of the invention to be used in the (processing) methods of the invention.

Claim 20; "mutant line"

- "Mutant line" was defined on page 16, lines 15 to 17 of the application as filed as a line possessing a mutation.

Claims 2 and 23; amendment of the stachyose content from "less than 19 $\mu\text{mol/g}$ " to "less than 15 $\mu\text{mol/g}$ "

- On page 7, lines 28 to 33, the application as filed referred explicitly to a heritable phenotype of a seed stachyose content of less than 15 $\mu\text{mol/g}$ (as is).

Claim 14 to 17; "having a stachyose content of less than 45 $\mu\text{mol/g}$ "

- The introduced feature "having a stachyose content of less than 45 $\mu\text{mol/g}$ " found a basis e.g. in corresponding claims 16 to 19 of the application as filed.

Sufficiency of disclosure

- The appellant had not provided any evidence that it had attempted to identify further *stc1x* containing soybean lines, e.g. by using mutagenesis steps, and had failed.
- The patent taught two lines having the *stc1x* allele, i.e. LR28 and LR484. Further lines could therefore be obtained by breeding these lines with other soybean lines as the trait was shown to be heritable and stable. The patent taught furthermore appropriate methodology for the mutagenesis protocol enabling the skilled person to reproduce the mutagenesis, screening and allelism test steps to generate LR484 and thus generate further *stc1x* mutants having suitably low levels of stachyose. Armed with this information and the necessary research tools the skilled person was readily able to follow the teaching without undue burden and without inventive input to identify soybeans falling within the claim scope.
- Seeing that the patent taught the skilled person that a mutation at a single locus was required to

achieve low stachyose lines having the *stc1x* genotype, the skilled person would be confident of being able to reproduce the mutagenesis experiments to obtain a *stc1x* allele.

- Document (14a) provided no evidence that following the protocols disclosed in the patent with a different starting line would not similarly result in a desired mutant.

- The case underlying decision T 727/95 of (OJ EPO 2001, 1) was different. Here the finding of undue burden by the board was justified by the fact that the specification did not teach which characteristics to look for in a screen for identifying the new strains (see points 9 and 10 of the reasons). Furthermore mutation was neither described nor suggested in the specification for this purpose. The specification of the patent in suit in contrast provided a wealth of information regarding the steps that are required to be performed at each stage of the process.

Novelty

- Processing of soybeans into milk generated an altered product with composition different from the soybeans from which it was derived. When processing was applied equally to both normal soybeans and low stachyose soybeans the end products, i.e. soy milk, was different because of the different starting materials, i.e. a conventional soybean having normal levels of stachyose would generate milk with proportionally

more stachyose than milk that is made from a low stachyose soybean according to the invention. The conventional soybean milk of documents (26) and (27) had thus higher stachyose content than the subject-matter of claim 14, prepared from the soybeans of the invention.

- There were in addition to the stachyose level feature many further properties of the low stachyose soybeans that were carried over into the soy milk, which could be measured, alone or in combination, to determine whether soy milk had been made from the low stachyose soybeans according to the invention or not such as a combination of low stachyose and high galactinol which was associated with the presence of the stclx allele in the soybean line tested, the ratio sucrose vs. raffinose and stachyose which was higher in the soybeans of the invention than in conventional soybeans and the high galactose levels, compared to those found in conventional soybeans and milk.

- The soy milk disclosed in document (28), from which stachyose has been removed enzymatically, could be distinguished from soy milk made from the low stachyose soybeans according to the invention by measurement of the other characteristic properties of that soy milk referred to above seeing that although the stachyose might have been removed enzymatically other properties were not similarly altered. Whilst enzymatic treatment might or might not affect the levels of some saccharides to different degrees, the levels of

different saccharides in soy milk from soybeans of the invention provided a unique and distinctive "fingerprint" that was readily determinable and was not mirrored in soy milk from any conventional soybeans.

- For the same reasons as apply to claim 14, the subject-matter of claims 15, 17 and 18 was new over the prior art.

Inventive step

- The patent taught for the first time that low stachyose phenotype soybeans with less than 30 $\mu\text{mol/g}$ of stachyose existed or could be generated e.g. by mutagenesis and that there was a single genetic locus responsible for the characteristic.
- This was even more pronounced with respect to the teaching in the specification of the "modifier" effect, whereby crossing with elite lines (as required in claim 1) further reduced the stachyose levels. The presence of modifier genes in elite lines and their effect to further reduce stachyose levels in progeny could not have been predicted and was in no way foreshadowed in the prior art.
- Document (4) merely speculated as to whether it would be possible to obtain stable and heritable low stachyose soybean lines through breeding. This did however not provide motivation for the skilled person to screen the USDA Soybean Germplasm Collection, as it has not even been shown that a

stable and heritable low stachyose line might be obtainable.

- It was known at the priority date that although certain low stachyose lines existed, these were neither stable nor heritable. The patent provided in paragraphs [0056] and [0057] the method to determine the stachyose level of the soybean seeds as referred to in the patent claims. Annex 6 provided a comparison of the stachyose levels as measured in prior art documents (4), (18), (19) and (20) with the soybeans of the present invention as well as measurements of the prior art lines made in the specification ("Spec") or submitted during the opposition procedure ("Subs"). The Annex revealed that, when measured in accordance with the standard method of the patent, the stachyose values quoted in document (19) as well as (20) were understated and when assessed correctly showed values of from 57 to 107 $\mu\text{mol/g}$ (based on undried seed) stachyose.

- There was thus nothing in the prior art to suggest that a significant reduction of stachyose to levels lower than 30 $\mu\text{mol/g}$ (based on undried seed) could be achieved. Even by selecting lines from the lower end of the range of stachyose observed in documents (19) and (20), i.e. stachyose levels of at best 57 $\mu\text{mol/g}$ (based on undried seed) the skilled person would not considered it possible to breed lines well outside the indicated range of phenotypic variation to a half of the lowest identified level.

IX. The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked. The respondent (patentee) requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of claims 1 to 23 of the new main request filed at the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Article 11(3) RPBA

2. According to Article 11(3) of the Rules of Procedure of the Boards of Appeal (RPBA) the board is not obliged to delay any step in the proceedings, including its decision, by reasons only of the absence at oral proceedings of any party duly summoned who may then be treated as relying only on its written case. In the present case the board could therefore take a decision at oral proceedings, notwithstanding the announced absence of the duly summoned appellant.

Added matter

3. In its statement of the grounds of appeal, the appellant has only referred under Article 100(c) EPC (see section VII, above) to particular features contained in the claims of the main request before the opposition division which had already been contained in the claims as granted and has not raised any objections to the claims of the main request before the opposition division under Article 123(2) EPC, i.e. concerning

those amendments made during the opposition procedure over the granted claims. The board sees no necessity to depart from the decision of the opposition division that those amendments comply with the requirements of Article 123(2) EPC.

4. The outstanding issues under Article 100(c) EPC are dealt with first in points 5 to 7. The additional amendments contained in the claims of the request before the board as compared to the claims before the opposition division are dealt with in points 8 to 9. Finally, point 10 deals with the correction of clerical errors in the claims (Rule 88 EPC).

Article 100(c) EPC

Claim 1; "said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding"

5. The feature "said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding" contained in claim 1, and which was identically contained in claim 1 as granted, has no explicit basis in the application as filed.
 - 5.1 Dehulling has however been disclosed for example on page 21, line 13 and technical details of soybean dehulling can be taken from page 56, lines 5 to 10 of the application as filed. Cracking has been disclosed for example in claims 9 to 11 and 14, in steps (a) and technical details can be taken from page 55, line 35 to page 56, line 5 and grinding of soybeans has been disclosed on page 20, line 5.

- 5.2 The board notes that all three disclosed processing methods, i.e. dehulling, cracking and grinding are necessarily and by definition mechanical and result in processed soybeans which are non-viable. This has not been contested by the appellant who however has argued that following *inter alia* decision T 354/97 of 3 May 2000, the case law denied that the disclosure of specific examples supported a generalisation in regard to the category to which the example belongs.
- 5.3 The board considers however that in the case of the patent in suit, the gist of the application justifies allowing the contested generalisation, seeing that contrary to e.g. the case underlying decision T 354/97, *supra*, the generalisation does not extend to such processing methods which the skilled person would not clearly and unambiguously consider to also be part of the invention.
- 5.4 As to the argument of the appellant that the patent application as filed considered "soybeans" that had undergone mechanical processing no longer to be "soybeans" but rather "processed soy protein products" and that therefore the feature "said soybeans being non-viable as a result of mechanical processing such as dehulling, cracking or grinding" in claim 1 found no basis in the application as originally filed, the board agrees with the respondent that this concerns a matter of clarity, which does not constitute a ground for opposition, rather than a matter of added matter.
- 5.5 For the above reasons, the board considers that the contested feature "said soybeans being non-viable as a result of mechanical processing such as dehulling,

cracking or grinding" constitutes matter which is directly and unambiguously derivable from the application as filed.

Claims 5 to 9, 12, 14, 18 and 21; stachyose content of "less than 30 $\mu\text{mol/g}$ "

6. The board notes that the only mention of the feature "30 $\mu\text{mol/g}$ " is on page 7, lines 28 to 33 of the application in the context of breeding products stating that "*Preferred are seeds, plant lines producing seeds, plants producing seeds and the progeny of such plant lines, plants and seeds that have a heritable phenotype of a seed stachyose content of less than 30 $\mu\text{mol/g}$ (as is) or less than 15 $\mu\text{mol/g}$ (as is) respectively.*". The board considers however that none of the independent claims 5 to 9, 12, 14 and 18 require the processed product to have a stachyose content of less than 30 $\mu\text{mol/g}$, but that when properly construing these claims the back-reference to claims 1 to 4 merely requires the starting product for the processing, i.e. the soybeans as defined in claims 1 to 4 and thus the breeding products mentioned on page 7, to meet the stachyose content requirement. The board notes furthermore that in claim 21 the feature "30 $\mu\text{mol/g}$ " refers as well to the starting product as resulting product, both being breeding products as anticipated by the sentence on page 7. The board therefore sees no case for added matter relating to this feature.

Claim 20; "mutant line"

7. The notion "Mutant" is defined on page 16, lines 15 to 17 of the application as filed as "an individual, or

lineage of individuals, possessing a mutation". The application as filed demonstrates the allelism of both the *stc1a* and *stc1b* alleles in LR28 and LR484, respectively, whereby the latter allele was created by mutation (see example 2). Moreover, it is clear from the rather remarkable uniqueness of LR28 in the population of 14.000 PI lines tested (see page 32, line 23 and further) that the *stc1a* constitutes a mutant of the originally and ubiquitously occurring unmutated gene. For the above reasons the board considers that the qualification of LR28 in claim 20 as being a "mutant line" does not confront the skilled person with subject-matter which was not directly and unambiguously derivable from the application as filed.

Article 123(2) EPC

Claims 2 and 23; amendment of the stachyose content from "less than 19 $\mu\text{mol/g}$ " to "less than 15 $\mu\text{mol/g}$ "

8. Dependent claims 2 and 23 have been amended as compared to their granted counterparts in that the stachyose content is now indicated as being "*less than 15 $\mu\text{mol/g}$* ". The passage on page 7, lines 28 to 33, of the application as filed referred to above in point 10 refers explicitly to a heritable phenotype of a seed stachyose content of less than 15 $\mu\text{mol/g}$ (as is). Accordingly, the board is satisfied that the application as filed provides a basis for the referred to amendment in claims 2 and 23.

Claim 14 to 17, addition of "having a stachyose content of less than 45 $\mu\text{mol/g}$ "

9. The board is satisfied that claims 16 to 19 of the application as filed, which correspond to claims 14 to 17 as granted, qualify the respective products by the feature "having a stachyose content of less than 45 $\mu\text{mol/g}$ ". The amendment of claims 14 to 17 of the main request as compared to claims 14 to 17 as granted find therefore a basis in the application as filed.

Rule 88 EPC

10. Besides amendments referred to in the above paragraphs, the claims at various instances have been altered to correct clerical errors. In order to comply with conventional nomenclature the expression "Stc1x gene" in claims 1, 21 and 22 is now referred to as "**st**c1x gene". Furthermore, in step (b) and step (e) in claims 7 and 8, respectively, the expression "to obtained" was corrected to "to obtain". The board considers both corrections as obvious corrections in the sense that it is immediately evident that nothing else had been intended than what is corrected. Accordingly, they comply with the requirements of Rule 88 EPC.

11. For the above reasons the claims fulfil the requirements of Article 123(2) and Rule 88 EPC.

Article 123(3) EPC

12. The board is satisfied that all the amendments to the claims as compared to the claims as granted constitute either minor clerical corrections or result in the

restriction of the protection conferred by the claims. Accordingly, the claims of the main request comply with the requirements of Article 123(3) EPC.

Sufficiency of disclosure

13. Claim 1 relates to non-viable soybeans with a genotype that confers a heritable phenotype of seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed) wherein said soybeans are homozygous for a *stc1x* gene and capable of producing seed having a stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed). The board notes that the claim not only covers soybean lines derived from the specifically disclosed soybean lines LR28 and LR484, but also other non-viable soybean progeny derived from soybean plants comprising *stc1x* alleles different from the *stc1a* and *stc1b* allele, respectively, including such lines which are the result of further mutagenesis experiments.
14. Article 83 EPC stipulates that the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. This requires, in the present case, that the patent specification gives sufficient information for the production and identification of further soybean lines comprising alternative *stc1x* alleles to the *stc1a* and *stc1b* allele described and for the identification of such alleles.
15. The patent in suit, in paragraph [0039], discloses that the "*[a]pplicants teach two separate methods to produce the novel soybean genes of the present invention. The first approach involved exhaustive screening of*

existing soybean germplasm collections for sources of genes conferring low raffinose saccharide content. Applicants' germplasm screen was successful despite the failure of previous attempts by others to select and confirm germplasm with significant reduction of raffinose saccharides. The second approach marks the first successful attempt to induce a mutation conferring low raffinose saccharide content. Both approaches resulted in the discovery of soybean genes that can be used to develop soybean lines that are superior (in terms of reduced raffinose saccharide content) to any lines previously reported."

16. The first approach is further specified in example 1 of the patent in suit (paragraphs [0053] to [0070]) leading to the identification of line LR28. The second approach is emphasised in example 2 from paragraph [0071] to [0079], i.e. the successful creation by mutagenesis of a soybean line LR484. In relation to the latter approach it can be taken from paragraph [0071] of the patent in suit that "*[a] number of soybean lines were treated with a chemical mutagen, NMU (N-nitroso-N-methylurea), in an attempt to induce mutations that lower the raffinose saccharide content of soybean seeds. Lines treated included the elite lines Williams 82 and A2543, USDA germplasm lines A5 and N85-2176, and LR13. (...) The following protocol for the mutagenesis of LR13 is representative of the method by which the above lines were treated with NMU and advanced through subsequent generations to obtain populations that could be screened for low raffinose saccharide mutations."* What follows in example 2 is the actual description of the successful identification of LR484, i.e. a mutant soybean line having all the technical features required

by the subject-matter of claim 1 for the starting material.

17. In view of the above the board is satisfied that the patent provides sufficient information for the production and identification of further soybean lines, in particular in the context of example 2, i.e. in relation to the identification of further such soybean lines by means of mutagenesis protocols, comprising alternative stc1x alleles to the stc1a and stc1b allele described. Furthermore, in view of the disclosure of the allelism test at the end of example 2 in paragraphs [0077] to [0079], the skilled person is in a position to determine the allelism of any newly identified mutant soybean line isolated having low raffinose saccharide content with the disclosed stc1a and stc1b allele.

18. The appellant has argued that for any soybean line with a low stachyose other than the exemplified LR28 the skilled person would have to perform the experiments disclosed in either of the two examples, i.e. performing all steps to make the invention, such as assaying the stachyose content, determining heritability of the trait involving performing crossing experiments, performing the allelism test and, in addition for the mutagenesis protocol, performing mutagenesis experiments. This constituted undue experimentation depending on a chance event, a situation said to contravene the requirements of Article 83 EPC in decision T 727/95 (OJ EPO 2001, 1).

19. The board notes that it is also established case law of the boards of appeal that an application or a patent

may only be objected to for lack of sufficiency of disclosure if there are serious doubts, substantiated by verifiable facts (see decision T 19/90, OJ EPO 1990, 476). Although the appellant has argued serious doubts in the framework of decision T 727/95, *supra*, the appellant has not provided any proof that reworking either of examples 1 or 2 of the patent would not, in addition to the particularly disclosed soybean lines, result in such soybean lines which likewise provide suitable starting material for the method defined in claim 1 and thus reproducing this example would produce only chance events. In fact, seeing that the patent factually teaches the skilled person that a mutation at a single locus was required to achieve low stachyose lines having the *stclx* genotype, the skilled person, rather than have doubts, would not be hesitant to reproduce the mutagenesis experiments to obtain a *stclx* allele.

20. The board furthermore agrees with the respondent that the present case differs from the case underlying decision T 727/95, *supra*, in which the finding of undue burden by the board was given because the specification did not teach which characteristics to look for in a screen for identifying the new strains differing from the exemplified strains (see points 9 and 10 of the reasons). Indeed, the provision of microorganisms other than the deposited ones or derivatives thereof required the testing of 4000 mutagenesis survivors for stable cellulose production at high rate involving the culturing of each in 14 litre fermentors. Although this might be a routine method the board considered it nevertheless undue burden because success relied on a chance event and there was no evidence that such chance

events occur and can be identified frequently enough to guarantee success. Furthermore mutation was neither described nor suggested in the specification of the patent as a possible route for identifying *Acetobacter* strains of the invention.

21. In contrast, the specification of the patent in suit provides plenty of information regarding the steps that are required to be performed at each stage of the process. The patent teaches two lines having the *stc1x* allele, i.e. LR28 and LR484. Further lines can therefore be obtained by breeding these lines with other soybean lines as the trait is heritable and stable. The patent teaches furthermore appropriate methodology for the mutagenesis protocol enabling the skilled person to reproduce the mutagenesis, screening and allelism test steps to generate LR484 and thus generate further *stc1x* mutants having suitably low levels of stachyose (see above). Armed with this information and the necessary research tools the skilled person is therefore in the present case readily able to follow the teaching without undue burden and without inventive input to identify soybeans falling within the claim scope.

22. The board does furthermore not agree that reworking the examples would amount in making the invention as such again, although the board concedes that, as it is not unusual in genetic engineering, a considerable amount of time and effort may be necessary to do so. This, however, is a situation different from the one with which the board in the case T 727/95, *supra*, was confronted. Here, once the skilled person is taught by the patent in suit that further *stc1x* alleles can be

found, reworking may be cumbersome but does not constitute undue burden.

23. Finally the appellant has argued that document (14a) indicated that mutagenesis as such was a matter of chance and that it was rarely possible to predict mutagenesis frequencies in plant breeding. In this context the board notes however that, as established in points 15 to 17 above, the patent in suit teaches the skilled person in a comprehensive manner the experimental protocols for successfully providing required plant lines alternative to the exemplified lines LR28 and L484. The appellant's argument must therefore fail.

24. For the above reasons the board considers that the claimed subject-matter complies with the requirements of Article 83 EPC.

Novelty

25. The appellant has objected to the novelty of the subject-matter of claims 14, 15, 17 and 18. The board is satisfied that the subject-matter of the remaining claims is novel over the prior art.

26. The subject-matter of claim 14, 15, 17 and 18 is soy milk; undenatured, defatted soy protein products; heat-processed, defatted, flash-desolventized soy protein products and soy protein concentrate products, made from a soybean as defined in claim 1, respectively.

27. The appellant has argued that the corresponding products made from conventional soybeans as disclosed

in documents (26) and (27) (for claim 14), in documents (11) and (28) (for claim 15), in document (6) (for claim 17) and in documents (6) and (11) (for claim 18) could not be distinguished from those as claimed, seeing that the processing steps abolished the features characterising the soybeans of the invention and were therefore not carried through on the claimed protein products. Accordingly, and in particular, it was not possible for a skilled person to determine for a given soy milk from which soybean the soy milk was made because the stachyose content changed during the production process and the presence of a *stc1x* allele could not be determined due to the absence of any molecular characterisation of the *stc1x* allele in the patent.

28. The board notes however that, as submitted by the respondent and as can be taken from annex 5, when the processing of soybeans into milk was applied equally to normal soybeans and low stachyose soybeans the resultant soy milk could very well be distinguished from milk made from conventional soybeans when determining the ratio sucrose vs. raffinose + stachyose which is 10 to 20 times higher in the soymilk of the invention.

The board notes furthermore that from the data in table 3, table 5 and table 9 of the patent in suit, it can be inferred that the soybeans of the invention, contrary to conventional soybeans, demonstrate a substantially increased galactinol concentration, i.e. more than 10 times higher, whereby the ratio stachyose vs. galactinol is about 100 to 200 times lower in the soybeans of the application. The respondent has

submitted, and the appellant has not denied, that also this feature was carried over into the soy products when made of the soybeans of the invention, i.e. in the processed products of claims 14, 15, 17 and 18. The board therefore concludes that the products made from the soybeans of claim 1 are distinguishable from the above quoted corresponding prior art products.

29. The above considerations are in no contrast with the general approach in the case law of the boards of appeal (see e.g. decision T 20/94 of 4 November 1998) which holds that despite the fact that a product-by-process claim is characterised by the process for its preparation, it nevertheless belongs to the category of claim directed to a physical entity and is a claim directed to the product per se and that irrespective of whether the terms "directly obtained", "obtained" or "obtainable" is used in the product-by-process claim, it is still directed to the product per se and confers absolute protection upon the product.

30. The appellant has furthermore argued that the soy milk disclosed in document (28), from which stachyose has been removed enzymatically, also could not be distinguished from soy milk made from the low stachyose soybeans according to the invention. The board agrees however with the arguments of the respondent that other characteristic properties of that soy milk which are not similarly altered by the enzyme ("carbohydrase"; an enzyme preparation which is capable of hydrolysing a saccharide containing at least one uncommon linkage, such as α 1,6; see document (28), column 2 lines 41 to 43) remain a possible distinguishing factor with respect to its source soybean. Thus, whilst enzymatic

treatment might or might not affect the levels of some saccharides to different degrees, it would appear from the respondent's submissions that the levels of different saccharides in soy milk from soybeans of the invention provide a unique and distinctive "fingerprint" that is readily determinable and is not mirrored in soy milk from any conventional soybeans.

31. In the absence of any evidence to the contrary and when following the accepted principle in the case law of the boards of appeal that it is not justifiable to decide that a document is prejudicial to novelty on the basis of probability but rather that when a patent is revoked for lack of novelty, the department concerned has to be sure, having taken all the facts and arguments put forward during the proceedings into consideration, that the revocation is justified.
32. The board thus concludes from the above considerations, that the products of claims 14, 15, 17 and 18, made from the soybeans of claims 1 to 4 are distinguishable from the corresponding prior art products.

Inventive step

33. Claim 1 is directed to non-viable soybeans with a genotype that confers a heritable phenotype of seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed).
34. For assessing whether or not a claimed invention meets the requirements of Article 56 EPC the boards of appeal apply the "problem and solution" approach, which requires as a first step the identification of the

closest prior art. In accordance with the established case law of the boards of appeal, the closest prior art is a teaching in a document conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications to arrive at the claimed invention.

35. The board concurs with the appellant and the respondent that in the present case document (4) qualifies as closest prior art in the sense of the case law. This document aims at devising "*an efficient breeding procedure for improving soybean seed quality by reducing the concentrations of stachyose and raffinose*" (page 50, lines 2 to 5). When testing fifteen soybean genotypes and five environments it was found that for each sugar component, including stachyose, the largest source of seed level variation was due to the genotype (page 60, lines 1 to 3). As can be taken from table 1 on page 65 of document (4), the lowest mean seed stachyose levels were measured in the genotypes PI86445 (3.00 mg/100 mg dry seed), Scott (3.05 mg/100 mg dry seed) and PI243545 (2.87 mg/100 mg dry seed) which correspond, in accordance with Annex 6, to 42 $\mu\text{mol/g}$, 42 $\mu\text{mol/g}$ and 40 $\mu\text{mol/g}$, respectively, based on undried soybean seed. The heritability estimates for the stachyose content ranged from 62% to 92% (Table 6). Based on genotypic correlation coefficients among seed sugars (Table 7) the authors of document (4) eventually concluded that "*greater progress toward lowering seed stachyose concentration would most likely result from combining selection for low stachyose concentration with selecting for high sucrose concentration.*".

36. The problem to be solved by the subject-matter of claim 1 in the light of the disclosure in document (4) is the provision of soybeans with a genotype that confers a heritable phenotype of low seed stachyose content. Example 1 and 2 of the patent in suit satisfy the board that this problem is solved by the claimed subject-matter, i.e. providing a heritable seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed).
37. Document (4) concerns the proposal of a breeding concept for providing soybeans having improved seed quality due to reduced concentrations of stachyose and raffinose, i.e. to use low stachyose lines to improve the seed quality of other lines. The lowest mean seed stachyose levels measured in document (4) were 40 $\mu\text{mol/g}$ based on undried soybean seed. Document (4) alone, therefore, does not render obvious the subject-matter of claim 1, because the skilled person's attention is not even drawn to the problem to further decrease the stachyose content, let alone to any solution of this problem.
38. It therefore needs to be established, whether or not, the disclosure in any further cited document rendered either the search for soybeans with a genotype that confers a heritable phenotype of seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed) or the establishment of such soybeans (e.g. by means of breeding or mutagenesis) obvious.
39. The appellant has argued that both documents (19) and (20) fulfilled this purpose as both described several soybean lines having a low seed stachyose content,

whereby document (20) discloses even soybean lines having a seed stachyose content of less than 30 $\mu\text{mol/g}$ (page 240, table 3). Hence, the skilled person was motivated to seek soybean lines with a heritable low stachyose phenotype and had every reason to expect that the technical problem could be solved by screening for such lines.

40. The board notes however that, as annex 6 reveals, when measured in accordance with the method of the patent, the stachyose values quoted in document (19) as well as document (20) were understated and when assessed correctly showed values ranging from 57 to 107 $\mu\text{mol/g}$ stachyose (based on undried seed), i.e. well above the 30 $\mu\text{mol/g}$ (based on undried seed) stachyose aimed at by the invention. Accordingly, and as argued by the respondent, even by selecting lines from the lower end of the range of stachyose observed in documents (19) and (20) the skilled person would not consider the breeding of lines well outside the indicated range of phenotypic variation to a half of the lowest identified level possible. Therefore, the passage in document (19) that "*[p]erhaps additional screening will reveal lines lower in stachyose than those found in this study, yet which are high in protein and oil*" (page 615, last sentence) would not teach the skilled person that such screening would provide results as claimed.

41. The appellant, in the context of claim 1, has merely argued the lack of inventive step on the basis of the combination of the teaching of document (4) and either document (19) or (20). The board is satisfied that the disclosure of none of the other documents cited during the procedure would render either the search for

soybeans with a genotype that confers a heritable phenotype of seed stachyose content of less than 30 $\mu\text{mol/g}$ (based on undried seed) or the establishment of such soybeans (e.g. by means of breeding or mutagenesis) obvious.

42. In view of the above considerations, the board is convinced that the subject-matter of claims 1 to 4, and by the same token the specifically disclosed soybean lines LR28 and LR484, is inventive.
43. Independent method claims 5 to 9, 12, 20 and 21 make use of the inventive soybeans or the specific soybean lines LR28 and LR484. Accordingly, the subject-matter of claims 5 to 13 and 20 to 23 had not been rendered obvious to a skilled person either.
44. The closest prior art for the subject-matter of product claim 14 is represented by the disclosure in document (28) of soy milk originating from conventional soybeans from which stachyose has been removed enzymatically. The problem to be solved by the subject-matter of claim 14 is therefore the provision of such soybean lines which render the enzymatic removal of stachyose in the process of the production of soymilk superfluous. Similarly, the closest prior art for the subject-matter of claims 15 to 19 are the respective soy-products produced from conventional soybeans. The problems to be solved by the inventions in these claims is considered to be therefore the provision of alternative respective products.
45. The subject-matter of claims 14 to 19 solves these problems by the provision of the products made from the

inventive soybeans of claim 1. The board is satisfied that characterising features of the soybeans of claim 1 carry through to the processed products made from such soybeans. For the same reasons as for the subject-matter of claim 1 therefore, the subject-matter of claims 14 to 19 was not rendered obvious to the skilled person.

46. Thus, the subject-matter of the claims of the main request involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of the following documents:
 - claims 1 to 23 filed at the oral proceedings
 - description: pages 2, 3, 6 to 32 of the patent specification and pages 4 and 5 filed at the oral proceedings
 - drawings: Figures 1A to 3 of the patent specification.

The Registrar:

The Chair:

R. Schumacher

U. Kinkeldey