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Datasheet for the decision of 7 February 2008

Case Number: T 1771/06 - 3.3.08

Application Number: 92901802.6

Publication Number: 0563189

IPC: C12N 15/56

Language of the proceedings: EN

Title of invention:
Genetically engineered modification of potato to form amylopectin-type starch

Patentee:
BASF Plant Science GmbH

Opponents:
Bayer BioScience GmbH
Cooperatieve Verkoop-en Productievereiniging van Aardappelmeel en Derivaten AVEBE B.A.

Headword:
Engineered potato/BASF

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
"Main request - novelty - yes"
"Inventive step - yes"
"Sufficiency of disclosure - yes"

Decisions cited:
G 0002/88, T 0190/99

Catchword:
- see points 1 to 5 (meaning of claim 1)

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1771/06 **-** 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 7 February 2008

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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 18 September 2006 concerning maintenance of European patent No. 0563189 in amended form.

Composition of the Board:

Chairman: L. Galligani
Members: F. Davison-Brunel
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. EP 0 563 189 with the title "Genetically engineered modification of potato to form amylopectin-type starch", claiming priority from the Swedish application SE 9004096 filed on 21 December 1990 was granted with 21 claims based on European application No. 92 901 802.6 (International publication No. WO 92/011376).

II. Two oppositions were filed on the grounds of Article 100(a) to (c) EPC. The opposition division maintained the patent in amended form on the basis of the third auxiliary request then on file, the preceding claim requests being refused for lack of inventive step.

III. The patent proprietor (Appellant I) and opponent 02 (Appellant II) duly filed notices of appeal and submitted statements of grounds of appeal. Appellant I' s statement of grounds of appeal filed on 26 January 2007 was accompanied by a main request and 11 auxiliary requests.

IV. All parties including opponent 01 (respondent) filed observations in answer to the statements of grounds of appeal. Appellant I also filed a new third auxiliary request, the previous third to eleventh auxiliary requests being accordingly renumbered fourth to twelfth auxiliary requests.

V. The board sent a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal (now Article 15(1) RPBA), stating its preliminary non-binding opinion.

VI. The two appellants filed further submissions in answer to this communication.

VII. Oral proceedings took place on 7 February 2008. Appellant I made the second auxiliary request filed on 26 January 2007 its main request. All other requests were withdrawn.

Claim 1 of the main request read as follows:

"1. A method of suppressing amylose formation in potato, characterized by genetically engineered modification of the potato by introducing into the genome of the potato tissue a gene construct comprising a fragment of the potato gene which codes for formation of granule-bound starch synthase (GBSS gene) inserted in the antisense direction, said fragment consisting of a nucleotide sequence selected from the group of the nucleotide sequences stated in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3, together with a tuber-specific promoter selected amongst patatin I and potato GBSS promoter."

Dependent claims 2 and 3 related to further features of the method of claim 1. Independent claim 4 was directed to an antisense construct comprising a tuber-specific promoter and the fragments SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO: 3 and dependent claims 5 to 7 related to further features of the antisense construct of claim 4. Claims 8 to 10 related to a vector comprising the specific sequences selected from SEQ ID No:1, No:2 or No:3. Claims 11 to 15 respectively related to a cell of a potato plant, a potato plant, a potato tuber, a seed from a potato plant or a microtuber of potato, the genome of

which comprised the antisense construct as claimed in any one of claims 4 to 7.

VIII. The following documents are mentioned in the present decision:

(3): Visser, R.G.F. et al., in "Antisense Nucleic Acids and Proteins, Fundamentals and Applications"; edited by J.N.M. Mol and A.R. van der Krol, M. Dekker Inc. N.Y.(USA), chapter 7, pages 141 to 155, 1991;

(5): Hergersberg, M., Inaugural-Dissertation zur Erlangung des Doktorsgrades der Mathematisch-Naturwissenschaftlichen Fakultät der Universität zu Köln, pages 1 to 79, 1988;

(8): Feenstra, W.J. et al., The European Workshop on Plant Biotechnology - Engineered Storage Products for the Agro Industry, Abstract No. 22, Workshop handbook, pages 73 to 75, Bad Soden a.T. (Germany), 15-18 April 1989;

(9): Visser, R.G.F. et al., First International Symposium on the Molecular Biology of the Potato, Abstract No.43; Bar Harbor, Maine (USA), 13 to 18 August 1989;

(14): Mol, J.N.M. et al., Plant Molecular Biology, Vol. 13, pages 287 to 294, 1989;

(16): EP-A-0 375 092;

(25): Kuipers, A.G.J. et al., Mol.Gen.Genet., Vol.246, pages 745 to 755, 1995;

(27): Table reporting experimental results for transgenic potato plants using antisense constructs comprising the GBSS promoter and antisense fragments of nucleotide sequences stated in SEQ ID No:1, No:2 and No:3 filed by appellant I on 20 January 2006;

(29): Jefferson, R. et al., Plant Molecular Biology, Vol.14, pages 995 to 1006, 1990;

(30): Visser, R.G.F. et al., Plant Molecular Biology, Vol. 17, pages 691 to 699, 1991.

IX. Appellant I's arguments in writing and during oral proceedings insofar as relevant to the present decision may be summarized as follows:

The meaning of claim 1:

The method of claim 1 was carried out with a gene construct said to "comprise" a fragment of the potato GBSS gene (see Section VII, supra). It was an established understanding in EPO practice that the word "comprise" had the broad meaning of "include" or "comprehend", and was thus "open". For this reason, the gene construct in addition to the obligatory elements listed in claim 1 may also contain other elements.

Article 54 EPC; novelty of claim 1

Document (3) could not be used to destroy the novelty of the claimed method making use of SEQ ID No.1 since this sequence enjoyed the priority date of 21 December 1990, ie. an earlier date than the publication date of this document (1991). It was also not detrimental to the novelty of the claimed method making use of SEQ ID No:2 or No:3 because these sequences contained introns and, besides, the promoter used in the experiments disclosed in document (3) was none of the patatin or GBSS promoters.

Article 56 EPC; inventive step
In relation to the claimed method being carried out with SEQ ID No:2 or No:3.

- SEQ ID No:2 and No:3 enjoyed priority as from the filing date of the application and, thus, document (3) published in the priority interval was the closest prior art. When reading document (3), the skilled person would have serious doubts that genomic antisense DNA could be used as a means to inhibit any gene, and document (5) was not helpful in lifting this uncertainty since, albeit disclosing genomic antisense GBSS DNA, it only described experimental data carried out with antisense cDNA. On the contrary, the patent specification clearly taught the skilled person that it was possible to suppress amylose production using antisense technology, thus providing a bona fide solution to the problem of producing amylose-free starch. Example 1 showed that the synthesis of the GBSS enzyme was inhibited when antisense GBSS genomic DNA was transcribed. The experimental evidence given in document (27) also demonstrated that all potato lines transformed with antisense constructs synthesized

essentially the same very small amounts of GBSS enzyme as a potato plant which produced no amylose at all when grown in the field.
As for post-published document (25), it did not provide evidence that the claimed method did not solve the problem of suppressing amylose formation "over the scope of the claim". It disclosed a gene construct which did not lead to suppression of amylose formation. Yet, this construct included potato antisense DNA immediately adjacent to the antisense GBSS DNA sequence. This antisense fragment would in fact be one extended fragment which, by definition, did not consist of SEQ ID No:1, No:2 or No:3 as required by the claim ie. did not fall within its ambit.

- Document (3) on its own did not make obvious the claimed invention: the suggestion on page 152 that "... fine tuning of the antisense technique may be achieved by using genomic antisense gbss constructs under different promoters" was of a very speculative nature and the only other passage where genomic constructs were discussed was to inform the reader that genomic sense constructs gave inexplicable results.
In addition it was hardly meaningful to combine the teachings of document (3) with those of document (14), since document (14) dealt with the suppression of floral pigmentation in petunia by antisense cDNA. The biological mechanism leading to colour formation was quite different from that of amylose formation. Furthermore, it was cDNA which had been used and when antisense cDNA fragments had been tested for their ability to suppress chalcone synthase, the results obtained were said to be unclear (page 291).

- Finally, it should be kept in mind that, at the filing date, the opinion was generally held that an excess of antisense RNA was necessary for inhibition to occur and that viral promoters were strong promoters from which high amounts of mRNA were likely to be produced. This suggested to the skilled person that endogenous promoters like the GBSS promoter should not be used.

For these reasons, the teachings of document (3), even if taken in combination with those of document (14), were not prejudicial to the inventive step of the claimed method carried out with SEQ ID No:2 or No:3.

Inventive step in relation to the claimed method being carried out with SEQ ID No:1

- SEQ ID No:1 enjoyed priority rights as from the filing date of the priority application and, for this reason, document (3) published in the priority interval was not relevant to the assessment of inventive step. The disclosures of documents (8) or (9), respectively regarded as closest prior art by the respondent and appellant II, were even much less relevant to inventive step than document (3). In these documents, there was no suggestion that antisense genomic DNA may be used instead of antisense cDNA. A fortiori, the use of fragments rather than of the full length antisense genomic DNA was not contemplated at all. Neither of the documents gave any information as to suitable promoters.

- The combination of the teachings of document (9) with those of document (14) could only be done with hindsight knowledge of the invention. There was no reason at all to combine the teachings of document (8) with those of

document (16) insofar as document (16) was not concerned with antisense technology, only mentioned antisense regulation of gene expression generically over four lines and was otherwise concerned with the transcriptional region of the patatin gene.

The claimed method carried out with SEQ ID No. 1 was inventive.

Article 83 EPC; sufficiency of disclosure

The patent in suit provided all necessary information and tools to isolate the claimed gene constructs and to use them in the claimed method. Document (27) provided ample evidence that potato lines transformed with constructs such as those claimed synthesized the GBSS enzyme at a very much reduced level which corresponded to that of a potato line which produced no amylose at all in field trials. The "negative" construct described in document (25) was not a construct in accordance with the claim since it contained antisense potato DNA in addition to GBSS DNA. It was thus irrelevant to sufficiency of disclosure. The skilled person would reproduce the invention without undue burden.

X. The arguments presented by appellant II and the respondent in writing and during oral proceedings insofar as relevant to the present decision may be summarized as follows:

The meaning of claim 1

Compared to claim 1 of the former main request, claim 1 of the present main request defined the fragments to be inserted in the potato tissues as consisting of SEQ ID

No:1, No:2 or No:3 rather than having either of these sequences. Inasmuch, the definition of the fragments had been delimited. Yet, this did not at all mean that the claimed subject-matter per se had been narrowed down insofar as the claim was still directed to a method to be carried out with a gene construct comprising a fragment of the potato GBSS DNA. Because of the use of the term "comprising", its scope remained "open". It was perfectly plausible that, in addition to the specifically mentioned fragments, the gene construct would encompass not only other parts of the GBSS potato gene such as leader or trailer or intervening sequences, but also any other DNA from the potato genome such as, for example, DNA immediately adjacent to the GBSS gene or even an additional full length antisense GBSS cDNA. The scope of the claim was thus unduly large and did not reflect the contribution to the art.

Article 54 EPC; novelty of claim 1

Document (3) (points 7.3 and 7.2.1) disclosed a method for inhibiting the expression of the potato GBSS gene, which made use of an antisense GBSS cDNA construct. The sequence of the antisense cDNA was not shown yet, it being antisense to potato GBSS cDNA, it would certainly contain antisense leader and coding sequences. Taking into account the breadth of present claim 1, this teaching was detrimental to novelty irrespective of which SEQ ID was comprised within the gene construct of claim 1.

Article 56 EPC; inventive step
In relation to the claimed method being carried out with SEQ ID No:2 or No:3

- These two sequences did not enjoy priority and, therefore, document (3) published in the priority interval was the closest prior art as it disclosed antisense inhibition of the GBSS gene by a full-length antisense GBSS cDNA. Furthermore document (3) suggested that "... fine tuning of the antisense technique may be achieved by using genomic antisense gbss constructs under different promoters".

- The problem to be solved was to provide an alternative method for the production of amylose-free starch. The alleged solution was to suppress amylose formation by the method of claim 1 to be carried out with antisense fragments of GBSS genomic DNA.
The patent provided no examples that the problem had been solved in this manner whereas such examples would have been essential taking into consideration that, as admitted by appellant I itself, the prior art (documents (3) or (5)) described the antisense technology as being entirely unpredictable.
In addition, experimental data (document (27) on file) showed that only one potato line out of 29 carrying the claimed constructs was negative for the presence of amylose, all others retaining GBSS activity to some extent.
As for post-published document (25), it described one construct carrying antisense GBSS genomic DNA which did not suppress amylose formation. It was true that this construct carried DNA immediately adjacent to the 3' end of the GBSS gene. Nonetheless, it fell within the definition of the gene construct in claim 1 because of the

very broad scope of this claim (see supra). For these reasons, the method of claim 1 was not a suitable solution to the above mentioned problem.

- In any case, document (3) suggested without any ambiguity that fine tuning of the antisense technique may be achieved by using antisense genomic GBSS constructs under different promoters and document (14) disclosed that, in petunia, the transcription of the antisense chalcone synthase gene fragments from the chalcone synthase endogenous promoter was effective to inhibit the synthesis of chalcone synthase.
The suggestion in document (3) coupled with the latter teachings made it obvious to use the gene construct mentioned in claim 1 to perform the claimed method.

It was also obvious to use the patatin or GBSS promoters for achieving antisense inhibition, taking into account that these promoters were known to be strong ones (documents (29) or (30)).

Inventive step in relation to the claimed method being carried out with SEQ ID No:1.

According to appellant II, document (9) was the closest prior art as it disclosed that suppression of GBSS protein synthesis occurred in the presence of homologous antisense GBSS DNA. The combination of this teaching with that in document (14) was said to render obvious the claimed subject-matter for the reasons given with regard to the combination of the teachings of documents (3) and (14).

According to the respondent, the closest prior art was document (8) which taught that GBSS activity was

completely abolished when a cDNA encoding antisense GBSS RNA was transcribed in the same cell. This teaching, combined with that in document (16) that it was possible to decrease the amount of a protein in a cell by using antisense technology, was said to render obvious the claimed subject-matter.

Article 83 EPC; sufficiency of disclosure

The patent specification added nothing to the art since the examples given only described recipes and not results which would have been obtained. Post-published document (25) showed that a construct which fell within the definition of the claimed construct did not lead to the suppression of GBSS protein synthesis. Document (27) disclosed transformed potato lines which still synthesized the GBSS enzyme. All these facts constituted evidence that the skilled person would be unable to reproduce the claimed subject-matter without undue burden.

XI. Appellant I requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed as second auxiliary request on 26 January 2007.

Appellant II requested that the decision under appeal be set aside and the patent be revoked. It also requested that the board's decision contain an interpretation of the scope of claim 1 of the main request.

Opponent 01 requested that the appeal by appellant I be dismissed.

Reasons for the decision

The meaning of claim 1

1. The claimed method is characterized by genetically engineered modification of the potato by introducing into the genome of the potato tissue a **gene construct comprising** a fragment of the potato granule-bound starch synthase gene (GBSS gene) inserted in the antisense direction, said fragment **consisting** of a nucleotide sequence selected from SEQ ID No:1, No:2 or No:3 together with a tuber-specific promoter selected among patatin I and potato GBSS promoter.

2. What is intended by the use of the expression "a gene construct comprising" was much discussed by the parties and this is indeed a most important point since, as explained in decision G 2/88 (OJ EPO 1990, 093), the purpose of the claims under the EPC is to enable the protection conferred by the patent to be determined. In this context, it is useful to turn to the principles of claim interpretation in accordance with the case law. In particular, T 190/99 of 6 March 2001 establishes that the patent must be construed by a mind willing to understand and not a mind desirous of misunderstanding.

3. Applying this precept, the board notices that claim 1 defines the antisense fragment of the GBSS potato gene which characterizes the gene construct as "**consisting**" of SEQ. ID No:1 or No:2 or No:3. This is an absolutely unambiguous definition. The said fragment is per se defined in a closed manner. There remains to elucidate what else the skilled person would understand a gene construct would have to comprise in addition to these

minimal requirements. For doing so, he/she would certainly take into account that the gene construct was made for the purpose of introducing the GBSS DNA fragment into the potato cells and integrating it into the genome. Accordingly, the gene construct would be thought to contain all necessary DNA elements for these steps to take place. And, in fact, the patent specification itself teaches on pages 5 and 6 that the relevant GBSS fragments must be inserted into a binary vector based on the T-DNA of Agrobacterium tumefaciens which contains the DNA elements necessary for replication in bacteria, transfer and integration into potato cells.

4. It was much argued by Appellant II that the scope of the claim extended to gene constructs which comprised **any DNA** in addition to the GBSS gene fragments. According to this interpretation, amylose formation would not be suppressed "over the scope of the claim" as post-published document (25) describes the construct pKGBA30 which comprises the GBSS DNA in antisense direction and in addition thereto, some other potato DNA at the 3' end of the GBSS gene, and does not express the GBSS enzyme.

5. However, as already mentioned above, it is not the board's reading of the claim that the gene construct is intended to contain other DNA than GBSS DNA, the listed promoters and any such DNA as would be expected from a gene construct for potato transformation. Of course, one may always conceive of specific embodiments which do not work. As it turns out, document (25) shows one such embodiment. However, this embodiment is not specifically referred to in the claims nor would it be envisaged by the skilled reader. Such conceivable non-working embodiments are not enough to cast doubt on the technical effect produced by

the claimed method which is embodied in the minimal requirements for amylose suppression which are mentioned in the claim. As already stated, the claim specifically refers with closed language to the characterising part of the gene construct and, in a legitimate attempt to generalize, leaves open the other structural elements necessary to operate the system. This is not an unusual claim formulation and the board sees no problem with it.

Article 54 EPC; novelty

6. At oral proceedings, some debate on novelty was allowed to take place as novelty was a ground of opposition and appellant I did not expressly object to it being a matter of discussion. Yet, novelty was not a point dealt with in the decision under appeal, nor is the board convinced that it was a ground maintained on appeal as no arguments were presented in this respect in the written part of the appeal proceedings except briefly in the very last of Appellant II's submissions on 7 January 2008. In any case, document (3) was the only document argued during oral proceedings to be detrimental to novelty and there is no doubt that it is not relevant in this respect. The argument that it was detrimental to the claimed method carried out with the DNA consisting of the nucleotide sequence SEQ ID No:1 fails since this embodiment was disclosed in the priority document and document (3) was published in the priority interval ie. it does not constitute prior art. In contrast, document (3) is prior art as regards the method being carried out with SEQ ID No.2 or No.3. Yet, it discloses in paragraph 7.2.1 antisense constructs carrying the full-length GBSS **cDNA** for the suppression of amylose production. This DNA is clearly different from that of SEQ ID No:2 or No:3 which

are genomic sequences containing introns. Novelty is, thus, acknowledged.

Article 56 EPC; inventive step in relation to the claimed method performed with the GBSS DNA SEQ ID No:2 or No:3

7. Document (3) is the closest prior art as it is concerned with the manipulation of granule-bound starch synthase activity and amylose content in potato by antisense genes. It discloses, in particular, that the expression of the full-length antisense potato GBSS cDNA under the control of a viral promoter (CaMV 35S) completely inhibits the expression of the GBSS gene which is accompanied by total absence of amylose (paragraphs 7.2.1 and 7.3). Genomic GBSS DNA is not mentioned in the document except when used in the sense orientation (page 152). However, the last sentence in the article reads:

"Finally, fine tuning of the antisense technique may be achieved by using genomic antisense gbss constructs under different promoters"

8. Starting from the closest prior art, the problem to be solved can be defined as the provision of an alternative method for suppressing amylose formation in potato.

9. The solution provided is a method whereby **specific** antisense **genomic** GBSS DNA **fragments** under the control of tuber-specific promoters are proposed for use in suppressing amylose formation. In the patent in suit, Example I explains the steps to be performed to obtain microtubers with inserted antisense constructs. The results to be expected from carrying out the method are described in paragraph [66]:

" ...Starch is extracted from the microtubers and analysed regarding the presence of the GBSS protein. In a polyacrylamide gel, the GBSS protein forms a distinct band at 60 kD, when the GBSS gene functions. If the GBSS gene is not expressed, i.e. when the antisense GBSS gene is fully expressed so that the formation of GBSS protein is inhibited, no 60 kD band can be seen on the gel."

While arguing that this was a theoretical example which had not been carried out, Appellant II and the respondent failed to provide any evidence that, if the method was carried out as described, it would not work. Appellant I provided experimental data to show that it did (document (27)). The presence of the GBSS enzyme is tested in 13 potato lines transformed with the gene construct SEQ ID No:1, 8 potato lines transformed with the gene construct SEQ ID No:2 and 8 potato lines transformed with the gene construct SEQ ID No:3. In all of them, the GBSS enzyme is found at a distinctly reduced level. Furthermore, for most of the transformed cell lines, the amounts of GBSS enzyme are only marginally higher than the amount of GBSS enzyme synthesized by a transformed potato line which does not produce amylose in the field. For these reasons, the board is convinced that the solution provided is a bona fide solution to the problem of suppressing amylose formation.

10. For the sake of completeness, it must be recalled that document (25) was argued to provide evidence that a construct comprising antisense GBSS genomic DNA did not supress amylose formation (pKGB30, page 748). Yet, this construct contains a fragment which does not entirely consist of GBSS genomic DNA (see points 3 to 5, supra). Therefore, it is not sufficient to conclude that the

solution provided is not a solution "over the scope of the claim".

11. The next question to be addressed is whether document (3) on its own or in combination with another document of the prior art would destroy inventive step. The above mentioned suggestion at the end of document (3) makes it obvious to try antisense genomic constructs for suppressing amylose formation. Yet, the claimed constructs are not made of full length genomic DNA. On the contrary, it is **fragments** of genomic DNA which have been used. In this respect, the combination of the teachings of documents (3) and (14) was argued to deprive the claim of inventive step.

12. Document (14) discloses antisense inhibition of floral pigmentation in petunia. The enzyme chalcone synthase (CHS) is said to be involved in the pathway, the end of products of which are responsible for a wide variety of colour shades. Antisense CHS DNA **fragments** encoding portions of RNA antisense to the CHS mRNA are tested for their effect on colour formation. It is found that the effectiveness of the antisense cDNA depends on which portions are being used. This result per se could not give the skilled person much confidence that amylose production could be suppressed by taking fragments of GBSS antisense DNA because there would remain the possibility that the "positive" fragments had some unique features which made them inhibitory. Furthermore, and most importantly, the antisense DNA which is used in document (14) is antisense **cDNA** - like in document (3) - whereas the antisense DNA SEQ ID No:2 and SEQ ID No:3 is antisense **genomic DNA**. This is an important difference insofar as the phenomenon of antisense inhibition requires that a duplex be formed

between antisense and sense RNAs. The antisense genomic DNA SEQ ID No.2 and No:3 and, consequently the antisense RNA transcript thereof will contain portions corresponding to introns - which are, of course absent from antisense cDNA/RNA. The skilled person, thus, had no expectation of success in using antisense genomic RNA for hybridising to mRNA.

13. For these reasons, inventive step is acknowledged for the claimed method to be performed with SEQ ID No:2 or No:3.

14. Appellant I also argued that the fact of using tuber-specific promoters in combination with antisense genomic DNA contributed to inventive step as the general belief at the filing date was that strong promoters such as viral promoters had to be used to obtain the excess of antisense RNA needed for antisense inhibition to take place. The respondent provided documents (29) and (30) to show that the tuber-specific promoters were known to be stronger than viral promoters when driving gene expression in tubers. Thus, it is not certain that the use of tuber-specific promoters adds to inventive step. Yet, this is not of relevance as a conclusion of inventive step was already reached on the basis of using genomic antisense DNA.

15. Finally, document (5) was also cited as relevant to inventive step. Like document (3), document (5) teaches the use of cDNA for antisense suppression of amylose production. On pages 33 and 34, it discloses partial sequences of genomic GBSS DNA, yet these are not used for antisense suppression. In the board's judgment, the teachings of document (5) are at best equivalent to those

of document (3). Document (5) need not be considered further in the assessment of inventive step.

Inventive step in relation to the method of claim 1 performed with a gene construct comprising SEQ ID No:1.

16. SEQ ID No:1 and the method of using it have the priority date of 21 December 1990 and, thus, document (3) published in 1991 may not serve as closest prior art. Appellant II and the respondent respectively argued that documents (9) or (8) were the closest prior art. These documents present abstracts of talks respectively given at a symposium and a workshop, prior to the priority date. Document (9) informs its readers that GBSS enzyme activity can be inhibited by a construct carrying antisense potato GBSS sequences and that the phenomenon leads to the suppression of amylose formation. The nature of this antisense DNA is not mentioned. Document (8) discloses that GBSS activity is completely abolished by an antisense GBSS **cDNA**. No suggestion is made in either of these documents of using antisense **genomic** DNA. These teachings are, thus, further away from the claimed method to be carried out with SEQ ID No:1 than was that of document (3) from the method to be carried out with SEQ ID No:2 or No:3. For this reason, neither of documents (8) or (9) taken alone or in combination with document (14) is sufficient to question inventive step.

17. The respondent also referred to document (16) as the document to be combined with document (8) for the assessment of inventive step. Document (16) is not in the field of antisense technology but is concerned with the regulatory regions of the patatin gene. The antisense technology is simply mentioned on page 4, lines 20 to 24

as the authors make the observation that it is useful if one wishes to decrease the amount of one given protein in a cell. The board is not convinced that document (16) would be taken into account when trying to achieve antisense regulation and, besides, it certainly is a less relevant document than document (14) which, when combined with document (3) was not found detrimental to inventive step.

18. The method of claim 1 to be performed with the antisense DNA fragment SEQ ID No:1 fulfils the requirements of Article 56 EPC.

Article 83 EPC; inventive step

19. In the board's judgment, the patent specification, pages 4 to 8 together with the SEQ ID No:1, No:2 or No:3, provides sufficient information for the skilled person to be able to reproduce the invention over the scope of the claim.

20. One argument against sufficiency of disclosure by appellant II and the respondent went to the fact that the experimental data in document (27) showed that some GBSS activity remained in the genetically modified potato lines. This is true but as already mentioned in point 9 supra, a residual GBSS enzyme activity was also found in a potato line which produced no amylose at all in field trials. It may be that the results observed in terms of enzyme activity reflect the sensitivity of the method rather than the ability to produce amylose at detectable levels. In any case, it is not claimed that the suppression of amylose formation should be absolute.

21. Finally, lack of sufficiency was argued on the basis that the potato line transformed with the plasmid pKGB30 in document (25) could still produce amylase. There again, reference is made to points 3 to 5 supra, where it is established that this plasmid contains potato DNA in addition to the GBSS DNA, which implies that it does not consist only of GBSS DNA and, therefore, is not relevant to enablement.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside;

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the main request filed as second auxiliary request on 26 January 2007 and the description and figures to be adapted thereto.

The Registrar The Chairman

A. Wolinski L. Galligani