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**Datasheet for the decision
of 11 June 2015**

Case Number: T 0915/10 - 3.3.04

Application Number: 06771226.5

Publication Number: 1885176

IPC: A01H5/10, C12Q1/68

Language of the proceedings: EN

Title of invention:

Soybean event MON89788 and methods for detection thereof

Applicant:

Monsanto Technology, LLC

Headword:

Soybean event/MONSANTO

Relevant legal provisions:

EPC Art. 53(b), 54, 56, 83, 84, 123(2)
EPC R. 26(4), 27(b), 27(c)

Keyword:

Novelty - (yes)
Inventive step - (yes)
Exceptions to patentability - plant varieties (no)
Exceptions to patentability - essentially biological process
for the production of plants (no)

Decisions cited:

G 0001/98, G 0002/07, G 0001/08, T 0065/82, T 0019/90,
T 0356/93, T 1054/96, T 0315/03, T 0083/05, T 1242/06,
T 0775/08, T 2239/08

Catchword:

see Reasons 43 to 54.



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0915/10 - 3.3.04

**D E C I S I O N
of Technical Board of Appeal 3.3.04
of 11 June 2015**

Appellant: Monsanto Technology, LLC
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St. Louis, MO 63167 (US)

Representative: v. Menges, Albrecht
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 30 November 2009 refusing European patent application No. 06771226.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman B. Claes
Members: A. Chakravarty
M. Blasi

Summary of Facts and Submissions

- I. An appeal was filed against the decision of the examining division to refuse the European patent application No. 06771226.5, filed as an International patent application and published as WO 2006/130436. The application claims priority from US patent application number 60/685,584 with a filing date of 27 May 2005 (the "priority application").
- II. The examining division held that subject-matter of the claims of the request submitted with the letter of 5 November 2008 did not meet the requirements of Articles 123(2), 53(b) and/or 56 EPC.
- III. Claims 2, 3, 6, 7 and 15 of the application as filed read:
- "2. A soybean plant or part thereof comprising event MON89788, wherein representative soybean seed comprising event MON89788 have been deposited under ATCC accession number PTA-6708.
3. A seed of the plant of claim 2, wherein the seed comprises event MON89788.
6. The soybean plant part of claim 2, defined as a cell, pollen, ovule, flower, shoot, root, or leaf.
7. The soybean plant of claim 2, further defined as a progeny plant of any generation of a soybean plant comprising said event MON89788.
15. A method of producing a soybean plant tolerant to glyphosate herbicide comprising introducing into the genome of said plant event MON89788".

- IV. The applicant (appellant) filed a statement of grounds of appeal and requested that the decision of the examining division be set aside with the order to grant a patent on the basis of a concurrently submitted set of claims. Oral proceedings were requested in case the board was not minded to allow this request.
- V. In a communication pursuant to Article 15(1) RPBA attached to the summons to oral proceedings, the board informed the appellant of its preliminary, non-binding opinion on some of the substantive and legal matters concerning the appeal, in particular as they related to Articles 53(b), 54 and 56 EPC.
- VI. In reply to the communication of the board, the appellant submitted a new main request and four auxiliary requests.
- VII. Oral proceedings before the board took place on 11 June 2015. During these proceedings, the appellant withdrew all previous requests and submitted a final new main request. At the end of the oral proceedings, the chairman announced the decision of the board.
- VIII. The claims of the final main request read:
- "1. A soybean plant, a seed, progeny plant of any generation or part thereof, the genome thereof containing SEQ ID NO:9, wherein the plant is obtainable by crossing a plant obtained from soybean seed deposited under ATCC accession number PTA-6708 and another plant.
2. The soybean plant part of claim 1, which is defined as a cell, pollen, ovule, flower, shoot, root, or leaf.

3. A method of producing a soybean plant tolerant to glyphosate herbicide as defined in claim 1, which method comprises introducing SEQ ID NO:9 into the genome of said plant by transformation of plant cells with heterologous DNA.

4. A DNA molecule comprising SEQ ID NO:9."

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

D1: Terry C. *et al.*, Eur. Food Res. Technol. 2001, 213, 425-431.

D4: Windels P. *et al.*, Eur. Food Res. Technol. 2001, 213 107-112.

D6: US-6 080 916

D11: Document entitled "MON89788 Event Selection Process", submitted with the appellant's letter dated 2 July 2012.

D12: Declaration of Cindy Arnevik including Figures 1 to 5, filed with the appellant's letter dated 8 May 2015.

X. The appellant's arguments can be summarised as follows:

Inventive step

The subject-matter of claim 1 was limited to soybean plants containing insertion event MON89788 which produced significantly higher yields than plants containing other events comprising a similar transgene. Soybean plants containing event MON89788 and plants

containing event 40-3-2, which were considered to represent the closest prior art, all exhibited tolerance to the herbicide glyphosate due to introduction of a variant 5-enolpyruvyl-3-phosphoshikimate synthase (EPSPS) into the soybean genome. However, a study had shown that soybeans having the A3244 genetic background and containing event MON89788 had an increased yield of 7-11% over soybeans of the same genetic background containing event 40-3-2. The study represented a comparison of near-isogenic lines, which were estimated to be 94% genetically similar, with the primary difference between them being the transgene construct and in particular, its location in the soybean genome.

Document D12, an expert declaration of Ms Cindy Arnevik, summarised the results obtained in a large number of yield assays for soybean plants containing the event MON89788. From these studies it was concluded that event MON89788 acted as a haplotype marker for exceptionally high yield in the A3233 background.

Plants containing the event MON89788 had been subject to a "vast number" of crosses. The trait of high yield was present in all herbicide tolerant progeny of such crosses, indicating that the physical link between the genetic elements responsible for improved yield potential and the T-DNA insert containing the genetic elements responsible for herbicide tolerance, had not been broken as a result of meiotic cross-over. Moreover, the evidence of improved yield presented in document D12 related to soybean lines having at least one parent in common containing either event MON89788 or event 40-3-2 (half sib lines) from 78 unique elite varieties, all of which confirmed a significant yield increase for soybean plants containing event MON89788.

Patentability

Essentially biological processes for the production of plants

The Enlarged Board of Appeal confirmed in its decisions G 2/07 and G 1/08 that methods for producing transgenic plants were not excluded from patentability and that methods of producing transgenic plants should not specifically mention methods of crossing and selection. However, the decisions did not exclude methods of producing a transgenic plant which comprised methods of crossing and selection without mentioning them explicitly.

Furthermore, the claimed method explicitly required transformation of plant cells with a heterologous DNA but did not mention sexual crossing and selection.

Plant varieties

The subject matter of claims 1 and 2 did not characterise a single plant variety. As outlined in document D12, a vast number of plants which comprised the event MON89788 had been generated. Although varieties fell within the ambit of the claims, the technical feasibility of the invention extended to any soybean plant containing the event.

- XI. The appellant's final request was that the decision under appeal be set aside and a patent be granted on the basis of the set of claims of the final main request as filed during the oral proceedings (see section VIII.)

Reasons for the Decision

Introduction to the invention

1. The invention concerns soybean plants which have been genetically modified so as to make them tolerant to the herbicide glyphosate. In plants, the phytotoxin glyphosate inhibits the enzyme 5-enolpyruvyl-3-phosphoshikimate synthase (EPSPS) in the shikimic acid pathway, which provides a precursor for the synthesis of aromatic amino acids. For the purpose of the invention, tolerance to glyphosate was achieved by the introduction into the plant genome of a modified gene encoding a variant of EPSPS having a low affinity for glyphosate by means of an *Agrobacterium tumefaciens* based transformation system. The gene was transferred to the soybean genome between the left and right borders of the Ti plasmid transfer DNA (T-DNA).
2. During *Agrobacterium* mediated transformation of plant cells, the T-DNA may be inserted at any location in the plant genome, the chromosomal position of this insertion being random and hence unpredictable. In the art, each independent insertion is termed a transgenic "event". The chromosomal location of a T-DNA insertion is reflected in the sequence of the DNA spanning the junctions between the insert and the soybean genome immediately flanking the insert.
3. The invention concerns soybean plants which have been derived from a cell containing such an event and which contain in their genome the particular transgenic insertion event MON89788, which as a result, *inter alia*, of its chromosomal position is responsible for a good expression of the EPSPS gene, leading to good tolerance to glyphosate. The sequences spanning the

junctions of the MON89788 insert and the soybean genome are represented by SEQ ID NOs: 1 and 3 (left junction) and 2 and 4 (right junction). SEQ ID NO: 9 represents the entire inserted DNA along with some flanking soybean genomic sequences.

Main request

Amendments - Article 123(2) EPC

4. Soybean plants, seeds, progeny plant of any generation or parts thereof containing event MON89788 are disclosed in claims 2, 3 and 7 of the application as filed (see Section III.). That plants and plant material with the event MON89788 contain SEQ ID NO:9 in their genome is disclosed on page 21, paragraph 1 of the application as filed.
5. The subject-matter of claim 2 finds a basis in claim 6 of the application as filed, while the method of claim 3 finds a basis in the disclosure of claim 15, in combination with the disclosure at page 8, lines 32 to 33 of the application as filed. That a transgenic event soybean plant tolerant to glyphosate can be produced by transformation of plants cells with heterologous DNA (*i.e.* the subject-matter of claim 4) is disclosed in Example 2 of the application as filed, in particular on page 21, line 3, in combination with the disclosure of the passage on pages 8, line 32 to page 9, line 13.
6. In view of the above considerations, the board is satisfied that the subject-matter of each of claims 1 to 4 finds a basis in the application as filed. Accordingly, the claims comply with the requirements of Article 123(2) EPC.

Clarity - Article 84 EPC

7. The board is satisfied that the claims meet the requirements of Article 84 EPC.

Construction of claim 1

8. The claim is for a soybean plant which contains in its genome the DNA sequence SEQ ID NO: 9, which includes the T-DNA insert of the invention flanked by the specific adjacent soybean genomic sequences, as found in event MON89788 (see Figure 1 and page 21, paragraph 1 of the application as filed).
9. The T-DNA insert in SEQ ID NO: 9 comprises *Agrobacterium tumefaciens* T-DNA left and right border sequences flanking a codon optimised coding sequence of the *aroA* gene from the *Agrobacterium* strain CP4 encoding the CP4 EPSPS protein linked to specific regulatory elements (see Table 3 of the application as filed).
10. Claim 1 embraces soybean plants containing SEQ ID NO: 9 in their genome that are **obtainable** by a process of sexually crossing a soybean plant obtained from (*i.e.* grown from) a seed deposited according to Rule 31 EPC under ATCC accession number PTA-6708 and another plant. The "*another*" plant used as the second parent in the cross may be any fertile soybean plant. Neither the deposited seeds nor the plants grown from them are individually claimed.
11. Also claimed are progeny plants of any subsequent generation of the plants mentioned in point 10., as well as seeds and parts of any of the above plants containing SEQ ID NO: 9.

Sufficiency of disclosure - Article 83 EPC

Support in the description - Article 84 EPC

12. No objections under Article 83 EPC of lack of sufficient disclosure or under Article 84 EPC of lack of support in the description were raised by the examining division either during the examination proceedings or in the decision under appeal. The board sees no reasons to raise objections of its own motion in this respect.

Novelty - Article 54 EPC

13. Roundup Ready[®] soybean plants comprising the event 40-3-2, which are disclosed in e.g. documents D1 and D4, differ from the subject-matter of claims 1 and 2, *inter alia* in the nature of the T-DNA/plant DNA junctions, which reflects the different integration site of the T-DNA in the soybean genome. The 40-3-2 event is located on chromosome 2 whereas the MON89788 event is located on chromosome 1 (see document D12, comment 2). The plants also differ in the structure of the EPSPS expression cassette used to create the event. Indeed, the 40-3-2 soybean plants comprise part of CaMV 35S promoter, an EPSPS chloroplast transit peptide sequence from *Petunia*, an *Agrobacterium* CP4 *epsps* gene and a 3' non-translated region for the nopaline synthase gene terminator (see document D4, page 107, right column, final paragraph), while the claimed plants contain the chimeric P-FMV/Tsfl promoter, a leader and intron sequence from the *Arabidopsis thaliana* *Tsfl* gene, the chloroplast transit peptide sequence from the *Arabidopsis thaliana* *epsps* gene, the *Agrobacterium* CP4 *epsps* gene, and the polyadenylation sequence from the pea gene encoding ribulose-1,5-

bisphosphate carboxylase/oxygenase (see Table 3 of the application).

14. Accordingly, the board is satisfied that the plants containing the event 40-3-2 disclosed in documents D1 and D4 are not detrimental to the novelty of the subject-matter of claim 1. Moreover, none of the other prior art documents cited during the examining proceedings deprive the presently claimed subject-matter of novelty. The reasons for recognising novelty of the soybean plants of claim 1 apply, *mutatis mutandis*, to the subject-matter of claims 2 to 4.
15. The subject-matter of claims 1 to 4 is therefore novel and meets the requirements of Article 54 EPC.

Inventive step - Article 56 EPC

Claims 1 and 2

The closest prior art

16. The subject-matter of claim 1 are particular soybean plants which are tolerant to glyphosate.
17. The board concurs with both the examining division and the appellant, that glyphosate tolerant Roundup Ready[®] soybean plants comprising event 40-3-2 disclosed in documents D1 and D4, represent the closest prior art for assessing inventive step of the claimed plants. Both the 40-3-2 soybean plants and those of the invention were conceived to be glyphosate tolerant. The expression cassette used to generate the former was structurally similar to that used to generate the claimed plants.

The technical problem and solution

18. The application as filed discloses that soybean plants containing event MON89788 are glyphosate tolerant. Moreover, *"a soybean line comprising the MON89788 T-type genomic region (T-type is combination of a transgene and the associated haplotype region of a plant genome) in its genome has an improved yield relative to a line comprising the previous 40-3-2 T-type genomic region"* (see page 16, lines 29 to 32).
19. Thus, the technical effect of the differences between the soybeans representing the closest prior art and those claimed, is an improved yield potential of the claimed soybean plants compared to those of the prior art.
20. Taking into account the structural and functional features distinguishing the plants claimed from those representing the closest prior art and the technical effect resulting from them, the objective technical problem to be solved can be seen as the provision of soybean plants with high tolerance to glyphosate and having an increased yield potential. The appellant agreed with this formulation of the objection technical problem.
21. Although the application as filed does not disclose any detailed experimental data relating to yield, it does contain an explicit reference to data presented in Example 3 of the priority application (see sentence bridging pages 16 and 17 of the application as filed). In view of this experimental evidence the board is satisfied that the technical problem is solved by the claimed soybean plants containing event MON89788. Moreover additional, post-published evidence in

document D12 (see comment 4) corroborates the improved yield.

Obviousness

22. The appellant did not argue that the particular expression cassette used to generate the soybean plants of claim 1 involved an inventive step. Indeed, it is also the board's view that the skilled person seeking to provide further glyphosate tolerant soybean plants had all the technical (genetic) components and methods required to construct a transformation vector to obtain glyphosate tolerant soybean plants at their disposal. Accordingly, the appellant's arguments in favour of inventive step focused on the improved yield achievable by the soybean plants as claimed.
23. In the decision under appeal, the examining division held that the improved yield of soybean plants containing event MON89788 was due to the genetic background of the plants containing the event, namely the high yielding elite soybean variety A3244 and not to any properties associated with the MON89788 event itself.
24. However, the appellant argued that the host soybean variety used in the yield comparisons reported in Example 3 of the priority application was variety A3244 for both events MON89788 and "40-3-2". Accordingly, the improved yield observed could not be ascribed to the genetic background used to host the MON89788 event. Rather, it was caused by a particular haplotype of the A3244 variety (where a haplotype was a collection of specific alleles in a cluster of genes on a chromosome that are inherited together) for which the MON89788 event acted as a marker. This finding was confirmed by

the priority application (see Example 3) and by document D12 (see page 4, comment 5).

25. In view of the appellant's argument, the board is satisfied that the soybean population designated variety A3244 although quite homogeneous in phenotype, contains a number of different haplotypes associated with different yield potentials. Accordingly, the initial cell and plant containing the MON89788 transgenic event was of a high yielding haplotype and the (random) insertion site of the T-DNA comprising the expression cassette of the invention happened to be in close physical proximity to a genetic region associated with improved yield potential of that haplotype. The evidence demonstrating an association between the MON89788 event and high yield derives from plants in which said event is present in homozygous form (see Example 3 of the priority application).

26. Neither document D1 nor any other document belonging to the cited prior art discloses that the variety A3244 contains various haplotypes of different yield potentials. Thus, the skilled person seeking to solve the objective technical problem (see point 20. above), would not have had any reason to believe that following the known methodology for generating and selecting a transgenic event associated with good glyphosate tolerance could be used to simultaneously select a haplotype associated with a high yield potential. The fact that in the plants of the invention the T-DNA insertion is closely linked to and therefore acts as a (selection) marker for improved yield was not predictable and would have been regarded as an element of surprise by the skilled person (*cf.* decision T 775/08 of 1 February 2011, points 12 to 12.4 of the

reasons and of decision T 2239/08 of 10 January 2013, point 19 of the reasons).

27. Both soybean plants homozygous (homozygous plants) and plants heterozygous (heterozygous plants) for the MON89788 event are subject-matter of claim 1. It could therefore be argued that, contrary to the homozygous plants, the heterozygous plants might not benefit from the "*element of surprise*" referred to above, because the relevant haplotype providing the high yield potential is paired with a different haplotype in such plants.

28. The board notes however that the skilled person seeking to introgress the MON89788 event together with the haplotype responsible for improved yield potential into populations of soybean other than variety A3244, would have to cross the soybean plants containing the MON89788 event with plants of the target population. This would inevitably generate heterozygous plants as an essential intermediate product. In view of the fact that the heterozygous plants carry the haplotype responsible for improved yield potential, they at least make a structural and functional contribution to the subsequent (inventive) homozygous plants, *i.e.* to the solution of the objective technical problem (*cf.* decision T 65/82, OJ EPO 1983, 327, concerning chemical intermediates, see Headnotes). The reasons for recognition of inventive step for the homozygous plants therefore apply *mutatis mutandis* to heterozygous plants.

29. In view of the above considerations, the board concludes that the soybean plants of claim 1 (including the seed and progeny plants of any generation) were not

obvious to the skilled person having regard to the state of the art.

30. The seeds and plant parts as subject-matter of claim 1, as well as the plant parts explicitly mentioned in claim 2, may be used to grow or regenerate a whole plant of the invention. The reasons for recognising and inventive step for the claimed soybean plants therefore apply *mutatis mutandis* to these seeds and plant parts.
31. The subject-matter of claims 1 and 2 therefore meets the requirements of Article 56 EPC.

Claim 3

32. The subject-matter of claim 3, a method comprising introducing SEQ ID NO:9 into the genome of a plant by transformation of plant cells with heterologous DNA, is similar to the processes known in the prior art for the transformation of plant cells with heterologous DNA conferring tolerance to glyphosate. It differs from these in the nature of the heterologous DNA (see for instance, the processes used to generate the plants disclosed in literature cited on page 2, paragraph 1 of the application as filed).
33. The claimed method is for the production of a soybean plant which is itself novel and inventive (see points 13. to 31. above). These findings play a decisive role in the assessment of the inventive step of the claimed method for its production because the technical effect of a production method is reflected in the product produced. Without prior knowledge of the soybean plants of claim 1 or of the technical effects associated with them, the skilled person could not, without inventive skill, have devised the claimed method for their

production (*cf.* see Case Law of the Boards of Appeal of the EPO, 7th edition 2013, Chapter I.D.9.17, "*analogy process*").

34. The subject-matter of claim 3 therefore meets the requirements of Article 56 EPC.

Claim 4

35. The DNA molecule of claim 4 comprises the entire T-DNA, as well as stretches of adjacent soybean genomic DNA that is contained within the genome of the plants and plant parts of claims 1 and 2 (see point 3. above). It may be used *inter alia* in a method of producing a soybean plant of claim 3 or in assays for detecting the presence of a DNA molecule specific to the event in a plant part extract or seed extract (see page 1, lines 12 to 14 of the application as filed). The DNA molecule as claimed therefore provides a definition of the haplotype providing high yield potential and therefore contributes to or makes use of the technical effects of the soybean plants of claim 1 and the reasons for recognising inventive step for the soybean plants of claim 1 apply *mutatis mutandis* to the DNA molecule as claimed.

36. Accordingly, the subject-matter of claim 4 meets the requirements of Article 56 EPC.

Patentability

Article 53(b) EPC - Plant varieties

Claims 1 and 2

37. Subject-matter of claims 1 and 2 are soybean plants, where the term "soybean" is used in the art as a synonym for the plant species *Glycine max*, i.e. the cultivated soybean (see application as filed, page 1, line 16). "Species" is the botanical taxon of the rank falling below the taxon "genus". The population of plants that constitutes a plant species includes within it, *inter alia*, sub-groupings known as plant varieties, as defined in Rule 26(4) EPC.
38. The herbicide tolerant soybean plants as subject-matter of claims 1 and 2 (including those plant parts that can be used to regenerate whole plants) are particularly characterised by the fact that they contain the T-DNA insert and a closely linked portion of the adjoining soybean chromosome characteristic of event MON89788 (see point 3. above). This structural feature provides these plants with an improved yield potential compared to soybean plants containing event 40-3-2 (see points 23. to 26. above).
39. Thus, the claimed group of plants embraces all the (indefinite number of) individual plants as defined by the presence of event MON89788 (*cf.* decision G 1/98, OJ EPO 2000, 111, point 3.1 of the reasons, last paragraph, and decision T 1242/06, OJ EPO 2013, 42, points 25 to 39 of the reasons). The board is therefore satisfied that the plants as claimed are not defined "*by the expression of the characteristics that results from a given genotype or combination of*

genotypes" (i.e. by the entire constitution of a plant or a set of genetic information, cf. Rule 26(4) EPC).

40. While the deposited seeds referred to in claim 1 may constitute a plant variety due to the fixed genetic background of the variety A3244 (see document D11, page 1, paragraph 3), these deposited seeds are not however individually claimed, although they do fall within the ambit of the claim.
41. In view of the above considerations, the board is of the view that the plants as defined by claim 1 do not constitute a plant variety, as defined in Rule 26(4) EPC. This consideration applies *mutatis mutandis* to the subject-matter of claim 2. Moreover, the technical feasibility of the invention of claims 1 and 2 with respect to improved yield is not confined to one plant variety or group of plant varieties, but applies to soybean plants in general.
42. Accordingly, the board is satisfied that the subject-matter of claims 1 and 2 does not constitute a plant variety or varieties and is thus not excepted from patentability by virtue of Article 53(b) EPC in combination with Rule 27(b) EPC.

Article 53(b) EPC - Essentially biological processes for the production of plants

Claim 3

43. Claim 3 is directed to a method for producing a soybean plant tolerant to glyphosate herbicide as defined in claim 1. Pursuant to Article 53(b) EPC (non-microbiological) essentially biological processes for the production of plants are excepted from

patentability. Accordingly, it needs to be assessed whether or not the method of claim 3 is excluded from patentability.

44. The Enlarged Board of Appeal has dealt in detail with the process exclusion of Article 53(b) EPC in the consolidated decisions G 2/07 and G 1/08 (OJ EPO 2012, 130 and 206, respectively).
45. The processes for the production of plants considered by this board (albeit in a different composition) in referring decision T 83/05 (OJ EPO 2007, 644, leading to decision G 2/07, *supra*) and in referring decision T 1242/06 (OJ EPO 2008, 523, leading to decision G 1/08, *supra*) were plant breeding processes and the claims explicitly mentioned process steps of sexually crossing and (subsequent) selection of plants.
46. The Enlarged Board of Appeal held that plant breeding processes "*were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. This phenomenon determined the genetic make-up of the plants produced, and the breeding result was achieved by the breeder's selection of plants having the desired trait(s)*" (see decision G 2/07, *supra*, point 6.4.2.3 of the reasons; the full paragraph on page 199).
47. In summary, the Enlarged Board of Appeal concluded, in the context of claims for methods explicitly mentioning process steps of sexually crossing and (subsequent) selection of plants that "[a] *non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants*

[was] *in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC*" (see decision G 2/07, *supra*, Headnote, Answer 1).

48. The subject-matter of claim 3 is a method for the production of a soybean plant tolerant to glyphosate herbicide. The resulting plant has an improved yield potential linked to the presence of SEQ ID NO: 9. The method is defined solely by the technical process step of introducing SEQ ID NO: 9 into the genome of the plant by transformation of plant cells with heterologous DNA, *i.e.* a genetic engineering step introducing heterologous DNA in plant cells. The board notes that the introduced trait is due directly to the expression of the inserted DNA and is not the result of a plant breeding method characterised by crossing and selection. Indeed, the method as claimed does not require nor define steps of mixing genes of plants by sexual crossing and subsequent selection of plants, either explicitly or implicitly.
49. Accordingly, the board is satisfied that the method of claim 3 is not of the type that the Enlarged Board of Appeal in its decisions G 2/07, *supra*, and G 1/08, *supra*, considered to fall under the exclusion of "essentially biological processes for the production of plants" pursuant to Article 53(b) EPC.
50. Rather, the board considers that the subject-matter of claim 3 is a method for the production of plants by means of genetic engineering techniques (in this case transformation), which involves laboratory techniques essentially different from breeding methods and which as such have been accepted in the case law to be patentable (see e.g. decisions T 356/93, OJ EPO 1995,

545, and T 1054/96 of 6 December 2000, not published in the OJ; and decisions T 19/90 (OJ EPO 1990, 476) and T 315/03 (OJ EPO 2006, 15), the latter two referring to genetic engineering of animals).

51. The board also notes that there is nothing in decisions G 2/07 and G 1/08 (*supra*) which would indicate that the Enlarged Board of Appeal was of the opinion that this practice ought to be reconsidered as a result of its analysis of the process exclusion in Article 53(b) EPC.

52. Indeed, when considering the issues dealt with in Answer 3, the Enlarged Board of Appeal rather endorsed, that patent protection is available "*for example, for genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant (cf. T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.*" (see decision G 2/07, *supra*, point 6.4.2.3, penultimate paragraph). It has already been established that the subject-matter of claim 3 neither requires nor defines crossing and selection steps, either explicitly or implicitly (see point 48., above). The board notes furthermore the reference made by the Enlarged Board of Appeal to decision T 356/93, *supra*, in the quoted passage in which this board, in a different composition, came to the conclusion that a process for producing a particular plant which comprised transforming cells or tissues of said plant with heterologous DNA, the regeneration of plants therefrom and optionally the biological replication of these plants was not excluded from patentability by virtue of

Article 53(b) EPC (see decision T 356/93, *supra*, point 40.1 of the reasons).

53. Furthermore, when considering patentability of plant breeding methods in the context of claims for methods including crossing and selection steps and additional steps of a technical nature and in contrast to the situation pertaining to processes containing a technical step which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants, the Enlarged Board of Appeal held that "*[i]f, [...] such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC*" (see decision G 2/07, *supra*, Headnote, Answer 3). This statement is considered by this board as confirming the patentability of methods for genetic engineering of plants (see decisions G 2/07 and G 1/08, *supra*).

54. In view of the above considerations, the board concludes that the subject-matter of claim 3 is not excluded from patentability under Article 53(b) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent on the basis of claims 1 to 4 filed as new main request during oral proceedings before the board, and a description to be adapted thereto.

The Registrar:

The Chairman:



P. Cremona

B. Claes

Decision electronically authenticated