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- (A)  Publication in OJ  
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**D E C I S I O N**  
**of 21 February 1995**

**Case Number:** T 0356/93 - 3.3.4  
**Application Number:** 87400141.5  
**Publication Number:** 0242236  
**IPC:** C12N 15/00

**Language of the proceedings:** EN

**Title of invention:**

Plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering

**Patentee:**

PLANT GENETIC SYSTEMS N.V., et al

**Opponent:**

Greenpeace Ltd.

**Headword:**

Plant cells/PLANT GENETIC SYSTEMS

**Relevant legal provisions:**

EPC Art. 53(a), 53(b)

**Keyword:**

"Contrary to 'ordre public' (no)"  
"Contrary to morality (no)"  
"Exception to patentability - plant varieties (yes) - main, first, second auxiliary request - general claim encompassing plant varieties not allowable"  
"Plant as product of a microbiological process (no)"  
"Exception to patentability - plant cells (no)"  
"Exception to patentability - essentially biological process (no)"

**Decisions cited:**

T 0049/83, T 0320/87, T 0019/90, T 0016/87, T 0544/89,  
T 0565/89, T 0290/86

**Headnote:**

- I. Under Article 53(a) EPC, inventions the exploitation of which is likely to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public" (cf. point 5 of the Reasons). However, a decision in this respect presupposes that the threat to the environment be sufficiently substantiated at the time the decision is taken by the EPO (cf. point 18.5 of the Reasons).
- II. The concept of "plant varieties" under Article 53(b) EPC, first half-sentence, refers to any plant grouping within a single botanical taxon of the lowest-known rank which is characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics (cf. point 23 of the Reasons).
- III. Plant cells as such cannot be considered to fall under the definition of a plant or of a plant variety. Rather they are considered to be "microbiological products" in the broad sense (cf. point 23 of the Reasons).
- IV. The term "microorganism" includes plasmids, viruses and all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory (cf. point 34 of the Reasons).
- V. The concept of "microbiological processes" under Article 53(b) EPC, second half-sentence, refers to processes in which microorganisms (or their parts) are used to make or to modify products or in which new microorganisms are developed for specific uses. Consequently, the concept of "products thereof" under Article 53(b) EPC, second half-sentence, encompasses products which are made or modified by microorganisms as well as new microorganisms as such (cf. point 36 of the Reasons).
- VI. "Technical processes including a microbiological step" (here: a process for producing a plant) may not simply be equated with "microbiological processes". Nor can the resulting final products of such technical processes (e.g. plant varieties) be defined as "products of microbiological processes" within the meaning of Article 53(b) EPC, second half-sentence (cf. point 39 of the Reasons).

VII. A claim is not allowable if the grant of a patent in respect of the invention defined in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability. Hence, a claim which encompasses plant varieties is only allowable, if the exception to patentability under Article 53(b) EPC, first half-sentence, concerning plant varieties does not apply, because the subject-matter of the claim is to be regarded as the product of a microbiological process (cf. points 40.7 and 40.8 of the Reasons).

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T 0049/83, T 0320/87, T 0019/90, T 0016/87, T 0544/89,  
T 0565/89, T 0290/86

**Headnote:**

(follows)



Case Number: T 0356/93 - 3.3.4

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 21 February 1995

**Appellant:**  
(Opponent) Greenpeace Ltd.  
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London N12PN (GB)

**Representative:** Alexander, Daniel  
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**Respondent:**  
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**Representative:** Gutmann, Ernest  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office dated 15 February 1993  
rejecting the opposition filed against European  
patent No. 0 242 236 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey  
**Members:** L. Galligani  
W. Moser

## Summary of Facts and Submissions

I. European patent No. 0 242 236 was granted on 10 October 1990 for thirteen Contracting States with forty-four claims based on European application No. 87 400 141.5. Eight claims were independent claims. Claims 1, 7, 14, 21 read as follows:

- "1. Process for controlling the action in plant cells and plants comprising such cells of a glutamine synthetase inhibitor when the former are contacted with the latter, which comprises causing the stable integration in the genomic DNA of said plant cells of a heterologous DNA including a promoter recognized by polymerases of said plant cells and a foreign nucleotide sequence capable of being expressed in the form of a protein in said plant cells and plants, under the control of said promoter, and wherein said protein has an enzymatic activity capable of causing inactivation or neutralization of said glutamine synthetase inhibitor.
  
7. Process for producing a plant or reproduction material of said plant including a heterologous genetic material stably integrated therein and capable of being expressed in the said plants or reproduction material in the form of a protein capable of inactivating or neutralizing the activity of a glutamine synthetase inhibitor, which process comprises transforming cells or tissue of said plants with a DNA recombinant containing a heterologous DNA including a foreign nucleotide sequence encoding said protein as well as the regulatory elements selected among those which are capable of causing the stable integration of said

heterologous DNA in said plant cells or tissue and of enabling the expression of said foreign nucleotide sequence in said plant cells or plant tissue, regenerating plants or reproduction material of said plants or both from the plant cells or tissue transformed with said heterologous DNA and, optionally, biologically replicating said last mentioned plants or reproduction material or both.

14. Plant cells, non biologically transformed, which possess a heterologous DNA stably integrated in their genome, said heterologous DNA containing a foreign nucleotide sequence encoding a protein having a non-variety specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognized by the polymerases of said plant cells.
  
21. Plant, non biologically transformed, which possesses, stably integrated in the genome of its cells, a foreign DNA nucleotide sequence encoding a protein having a non-variety-specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognised by the polymerases of said cells.

Independent Claim 18 concerned seeds characterised by the same features of the plant of Claim 21.

Independent Claims 24 and 29 related, respectively, to a process for selectively protecting the culture of a plant species and selectively destroying weeds, and to a

process for selectively protecting a plant species in a field against fungal diseases, wherein the said plant species had the same features as the plant according to Claim 21.

The further independent Claim 37 related to a vector for the transformation of plant cells.

II. Notice of Opposition was filed against the European patent by the Appellants (Opponents). Revocation of the patent was requested on the grounds of Article 100(a) EPC, in particular on the grounds that the grant of a patent for plant life forms and the exploitation of the patent was contrary to morality and/or "ordre public" [Article 53(a) EPC], that the claims relating to plants and to processes for their production were not patentable under Article 53(b) EPC and that plant products from any generation beyond the first one did not constitute an invention under Article 52 EPC.

III. The Opposition Division announced at the end of oral proceedings held on 15 December 1992 the decision to reject the opposition pursuant to Article 102(2) EPC because the patent met the requirements of the EPC. The reasoned decision was dispatched on 15 February 1993.

The main reasons given in the decision were as follows:

(a) The appearance of descendants of the primary plants could not be separated from the patented invention since they would not exist in the absence of the invention. The inclusion in the patent claims of herbicide-resistant plants and plant material of future generations did not lead to any legal uncertainty concerning the scope of the claims or their legal effect. Thus, no exclusion under Article 52 EPC could be applied.



(b) Opposition proceedings before the European Patent Office (EPO) were not a proper forum for discussing pros and contras of the genetic engineering of plants. The Opposition Division was not obliged by decision T 19/90 (OJ EPO 1990, 476) to perform an analogous balancing exercise of pros and contras. In any case, the present invention did not belong to that extreme category of inventions which could be regarded as so abhorrent to the vast majority of the public as to render the granting of a patent inconceivable, and which, therefore, were to be excluded from patentability under Article 53(a) EPC. The Appellants had not been able to prove the existence of risks and indeed it was impossible to determine with any degree of accuracy the true extent of the risks. Perceived risks could well change substantially during the life of a patent. The assessment of risks and the consequent regulation of the exploitation of the invention were a matter for other bodies to consider.

(c) As the granted claims were not restricted to a narrowly defined group of plants such as a variety, but related to a much broader group, according to decisions T 49/83 (OJ EPO 1984, 112) and T 320/87 (OJ EPO 1990, 71), their subject-matter was not excluded from patentability under Article 53(b) EPC. As for the process claims, according to decision T 320/87 (supra), they were not excluded because the impact of human intervention was decisive. This applied also to the later generations of plants.

IV. The Appellants lodged an appeal against the decision of the Opposition Division and submitted the Statements of Grounds together with further evidence in support of their case.

V. The Respondents (Proprietors of the patent) replied to the Appellants' statements in a letter dated 31 December 1993 with which were enclosed Exhibits A to C.

VI. In a communication pursuant to Article 11(2) of the rules of procedure of the Boards of Appeal, the Board outlined the issues to be discussed at oral proceedings and made some preliminary observations with particular reference to the previous decisions by the Boards of Appeal and to the historical documentation ("travaux préparatoires") relating to the EPC.

In particular, with respect to the issue of Article 53(b) EPC, the Board informed the parties that it wished also to consider the question whether any of the claimed subject-matter in the present case constituted an exception to patentability under this provision from the point of view of the second half-sentence of that article.

VII. In letters dated 27 October 1994 and 5 December 1994, the Appellants submitted a response to the Respondents' submissions and to the communication of the Board.

VIII. Oral proceedings took place on 20 December 1994.

During oral proceedings, the Respondents submitted three auxiliary requests, namely Claims 1 to 44 as first auxiliary request, Claims 1 to 42 as second auxiliary request and Claims 1 to 38 as third auxiliary request.

The claims of the first auxiliary request differed from the granted claims in that new Claims 18 to 23 replaced the granted Claims 18 to 23, all other claims remaining unchanged. Claim 23 therein read as follows:

"A plant which is obtained by the process of any of claims 7 to 13."

The claims of the second auxiliary request differed from the granted claims in that new Claims 18 to 21 replaced the granted Claims 18 to 23, all remaining claims being either unchanged (Claims 1 to 17) or correspondingly amended and renumbered (Claims 22 to 42). Claim 20 therein read as follows:

"The plant cells of any of claims 14 to 17 which are contained in a plant."

In the third auxiliary request, the granted Claims 18 to 23 were deleted, all remaining claims being either unchanged (Claims 1 to 17) or correspondingly amended and renumbered (Claims 18 to 38).

IX. The Appellants submitted essentially the following arguments:

- (a) As plant genetic resources were the heritage of mankind, they had to remain available to all without restriction and to be preserved intact for future generations. Permitting patent protection for genetically engineered plants was against these principles. Moreover, there were concerns about the dominion that was sought to be exercised over the natural world.
- (b) The results of a survey in Sweden and of an opinion poll in Switzerland indicated that public opinion was against the patenting of genetically engineered, herbicide-resistant plants as technical inventions.

(c) The EPO being at the crossroads between science and public policy, was qualified to make value judgements about a given technology. When granting patents, the EPO had to take into primary consideration public interest which, in the specific case at issue, was the preservation of the environment. Although the EPO could not possibly engage in an exercise of imagining the not yet proven risks of a claimed technology, in the present case a lot of evidence demonstrated the environmental consequences and disadvantages of the claimed subject-matter. If a balancing exercise were done according to the guidance given in decision T 19/90 (supra), no incontrovertible upside of the exploitation of the invention could be found which could justify the granting of a patent. The plus side (removal of weeds) started with a disadvantage because the claims, in particular Claims 24 to 36 as granted, provided for an increased application of herbicides, which was not universally regarded as desirable (cf. the affidavit of Dr P. R. Beaumont and related evidence, in particular the report entitled "Crops Resistant to Glutamine Synthetase Inhibitors", 1991 - hereinafter **Beaumont**). The exploitation of the present invention resulted in serious, irreversible environmental risks:

- the treated plants themselves could become weeds [cf., for example, **Beaumont** (op.cit.); Fitter et al., Bio/Technology Vol.8, May 1990, page 473 - hereinafter **Fitter** -; Williamson, in "Herbicide resistance in weeds and crops: 11th Long Ashton International Symposium" I. C. Casely et al (eds), Butterworth, 1990, pages 375 to 386 - hereinafter **Williamson I**]; thus, instead of removing weeds, new weeds were created;

- Herbicide-resistance could spread to other plants [cf., for example, **Beaumont** (op.cit.)];
- the ecosystems could be damaged [cf., for example, Williamson, TIBTECH, Vol.6, No.4, April 1988, pages S32 to S35 - hereinafter **Williamson II**].

As shown by the article of Le Baron and McFarland in "Managing resistance to agrochemicals: from fundamental research to practical strategies", M. B. Green et al (eds), 1990, pages 336 to 352 (hereinafter **Le Baron**), even in the industry's view it was not desirable to develop herbicide-resistance in plants (see page 351, item 9).

- (d) In respect of Article 53(b) EPC, the Board, in the Appellants' view, had to decide in accordance with the established legal principles bearing in mind that the drafters of the EPC had specifically intended to exclude plant varieties.

Claims 14 to 23 as granted, although cleverly drafted in general terms, were in reality meant to cover plant varieties and this was admitted by the Respondents. As a matter of fact, the said claims related to a very narrow group of plants with a particular characteristic (herbicide-resistance) which was transmitted in a stable manner down the generations without the need for returning to the original parent, and which was intended to be part of the genetic modification of the relevant plants. This corresponded de facto to the definition of a plant variety, as defined by the International Convention for the Protection of New Varieties of Plants (UPOV). Thus, the claims were not allowable

under Article 53(b) EPC. In fact, when a claim covered something which was unpatentable, the whole claim was bad.

- (e) Claim 7 related to a biological process, not to a microbiological process. In fact, apart from the step of the integration of foreign DNA into the genome, which was an entirely random event, all immediately subsequent steps up to the replication of the plants or of the reproduction material, were biological. Thus, the process as a whole was essentially biological and was excluded from patentability under the terms of Article 53(b) EPC.

Also the plant material of Claims 14 to 23 which resulted from the said essentially biological process was not patentable under that article.

- (f) The subject-matter of Claims 14 to 23 was excluded from patentability also when the second half-sentence of Article 53(b) EPC was taken into account. This provision was not intended to provide patent protection for anything other than microorganisms derived from microbiological processes. The expression "microbiological process" did not mean "technical process" and was limited to microorganisms such as yeasts and the like (cf. Notice of the President of the EPO dated 11 December 1981, OJ EPO 1982, page 19; cf. Guidelines for Examination C-IV, 3.5). A wider interpretation was not possible. The subject-matter of the claims in question were not microorganisms, but plants.

Even if the expression "microbiological process" was broadly interpreted to cover any product of a process conducted in the laboratory at microscopic level and the first plant directly obtained thereby was considered to be the product of a microbiological process, it could not be said that subsequent generations of plants (e.g. the 10th generation of a herbicide-resistant plant) were something that with any reason could be regarded as the product of a microbiological process. In fact, the latter were the product of an essentially biological process, because they were spontaneously generated, and no intervening human process was required for their generation. Accordingly, such processes of generation and the resulting plants were not patentable under Article 53(b) EPC.

- (g) As regards the three auxiliary requests, the claims therein were merely "window-dressing" aimed at circumventing exclusion provisions and had to be rejected for the same reasons.

X. The Respondents argued essentially as follows:

- (a) The evidence of public opinion put forward by the Appellants was defective, because it was not concerned with this particular invention. Highly qualified scientists believed that biotechnology was a useful tool for ensuring sufficient food supplies for the growing world population which was a pressing moral question. The present patent did not affect existing genetic resources. On the contrary, it provided new ones.
- (b) The Appellants had not provided any positive evidence with respect to the risks which could possibly derive from the exploitation of the

present invention, such as the spreading of the herbicide-resistance gene to other plants or the transformation of crops into weeds.

Risk assessment was regulated by national or European directives. Institutions other than the EPO were highly competent in the technical assessment of risks and could under some circumstances prohibit the exploitation of an invention. No confusion should be made between the grant of patent rights for an invention on the one hand and the conditions of its exploitation on the other hand.

In any case, the present invention did not belong to the category of inventions which the public in general would have regarded as being so abhorrent or so dangerous that the grant of patent rights should have been inconceivable. The EPO should apply the exclusions from patentability under Article 53(a) EPC only in such extreme cases.

- (c) The exclusion from patentability under Article 53(b) EPC was limited to plant varieties (cf. decisions T 49/83 and 320/87 supra). The expression "plant varieties" in the said article was a legal definition, i.e. "protectable varieties", and should not be construed as a scientific definition. In fact, the rationale behind this was to exclude from patentability plant varieties because these were protectable under the UPOV. Plant varieties were finished products which should satisfy the UPOV requirements.

Although the present claims encompassed any type of plant, variety and non-variety, which had the stated feature, the claims could not be



artificially limited in some way to any specific plant variety. It was noted that the introduction of a disclaimer in the claims was not possible because one would not know what to disclaim.

Although the examples were indeed carried out on existing varieties, there were no indications that the patent should be limited to any type of variety. Some of the plants made according to the invention could later qualify to be a variety, but not necessarily. The claims also covered plant material that could not be recognised as a variety in any sensible way.

In any case, the question whether the claim covered plant varieties or not was a matter of claim interpretation which was not a ground of opposition (Article 84 EPC) and should be left to the national courts.

- (d) The drafters of the EPC did not want to exclude technical inventions from patentability. The idea behind Article 53(b) EPC, first half-sentence, was to exclude inventions made by essentially biological processes and to restore those made by technical processes in the second half-sentence of that article.

Plant cells were considered to be microbiological products under the current practice of the EPO. The claimed plants and seeds were the products of a technical process (cf. Claim 7) which consisted of three steps that could not be separated from each other, namely the integration of DNA into the genome of the cell, the regeneration of the cells or cultivated tissue, the biological replication of plants or reproduction material. The final

biological step was almost immaterial because the technical effect was determined by the introduction into the plant cells of the heterologous DNA, i.e. by the microbiological step of human intervention.

For these reasons, the exception to the exception to patentability under Article 53(b) EPC, second half-sentence, applied to the claimed plant cells, plants and seeds and patentability under Article 52 EPC was therefore restored for them.

- XI. The Appellants requested that the decision under appeal be set aside and that the patent be revoked.

The Respondents requested that the appeal be dismissed or, auxiliarily, that the patent be maintained on the basis of one of the three auxiliary requests submitted during oral proceedings (cf. Section VIII supra, second paragraph).

#### **Reasons for the Decision**

1. The appeal is admissible.

#### *Questions at issue*

2. Two main questions are at issue in the present case, namely:

- (a) whether any of the claimed subject-matter constitutes an exception to patentability under the provisions of Article 53(a) EPC; and

- (b) whether any of the claimed subject-matter constitutes an exception to patentability under the provisions of Article 53(b) EPC.

*Concepts of "ordre public" and "morality" under Article 53(a) EPC*

- 3. Article 53(a) EPC excludes from patentability "inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States".
- 4. As is apparent from the historical documentation, the EPC Working Party recognised that "there was no European definition of morality". Its members were, therefore, unanimously of the opinion that the "interpretation of the concept of morality should be a matter for European institutions" (cf. document IV/2767/61-E, page 7). The same applies to the concept of "ordre public" (ibid., page 8). Thus, prior to any assessment of the patentability of the claimed subject-matter under Article 53(a) EPC, the meaning of these concepts must be defined by way of interpretation.
- 5. It is generally accepted that the concept of "**ordre public**" covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public".

6. The concept of **morality** is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is **not** in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.
  
7. The second half-sentence of Article 53(a) EPC contains the qualification "that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States". This qualification makes clear that the assessment of whether or not a particular subject-matter is to be considered contrary to either "ordre public" or morality is not dependent upon any national laws or regulations. Conversely and by the same token, the Board is of the opinion that a particular subject-matter shall not automatically be regarded as complying with the requirements of Article 53(a) EPC merely because its exploitation is permitted in some or all of the Contracting States. Thus, approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute per se a sufficient criterion for the purposes of examination under Article 53(a) EPC.
  
8. From the historical documentation relating to the EPC it appears that the view according to which "the concept of patentability in the European patent law must be as wide as possible" predominated (cf. document IV/2071/61-E, page 5, point 2, first paragraph). Accordingly, the exceptions to patentability have been narrowly

construed, in particular in respect of plant and animal varieties (cf., for example, T 320/87 and T 19/90 supra). In the Board's view, this approach applies equally in respect of the provisions of Article 53(a) EPC.

9. The granting of industrial property rights in respect of "living" organisms, such as plants and animals, is the subject of intense debate in interested circles and is giving rise to some public concern. So far, three decisions of the Boards of Appeal have dealt with this issue, namely T 49/83, T 320/87 and T 19/90 (supra). In decision T 49/83, it was stated that "no general exclusion of inventions in the sphere of animate nature can be inferred from the EPC" (cf. point 2 of the Reasons). However, of the quoted decisions, only decision T 19/90 dealt specifically with the issue of the exception to patentability under Article 53(a) EPC (cf. point 5 of the Reasons). In that decision, it was held that, since the case at issue was concerned with the genetic manipulation of animals, which was undeniably problematic in various respects (suffering of the animals, risks for the environment, etc.), there were "compelling reasons to consider the implications of Article 53(a) EPC in relation to the question of patentability". The then competent Board considered that the decision as to whether or not Article 53(a) EPC was a bar to patenting the invention at issue depended "mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other". As this had not yet been done by the Examining Division, the case was remitted to the latter. In decisions T 49/83 (supra) and T 320/87 (supra), claims directed to a propagating material and to hybrid plants, respectively, were considered allowable under the provisions of the EPC.

10. The Board notes that both the historical documentation and the above-quoted case law recognise that, in principle, patents may be granted in respect of inventions concerning plants or animals (excluding plant or animal varieties) as well as inventions relating to processes of a technical nature for their production (cf., in particular, T 19/90 supra, point 4.10 of the Reasons as well as document IV/2071/61-E, page 6 of the EPC Working Party). Thus, in the Board's judgement, it can be inferred from the above that seeds and plants per se shall not constitute an exception to patentability under Article 53(a) EPC merely because they represent "living" matter or, as submitted by the Appellants, on the ground that plant genetic resources should remain the "common heritage of mankind". In respect of the latter point, the Board observes that the patenting of wild-type plant resources which may be used as starting material is not at issue in the present case. That such resources should belong to the "common heritage of mankind" is therefore not in jeopardy.

11. Thus, under Article 53(a) EPC, the relevant question is not whether living organisms are excluded as such, but rather whether or not the publication or exploitation of an invention related to a particular living organism is to be considered contrary to "ordre public" or morality.

*Assessment of patentability with regard to the requirements of Article 53(a) EPC*

12. Although it may be difficult to judge whether or not a claimed subject-matter is contrary to "ordre public" or morality, the provisions of Article 53(a) EPC may not be disregarded by the EPO when assessing patentability (cf. T 19/90 supra, in particular, point 5 of the Reasons).

13. The question whether a claimed invention constitutes an exception to patentability within the meaning of Article 53(a) EPC will have to be answered in each particular case on its merits, based on the concepts of "ordre public" and morality as defined above (cf. points 5 to 7 supra). The right approach is to look at the particular facts of each case and to examine whether in the light of those facts the case ought to stand.
  
14. In the present case, it has to be decided whether the exploitation of any of the subject-matter claimed in the patent in suit is either likely to seriously prejudice the environment or contrary to the conventionally accepted standards of conduct of European culture.
  
15. In order to establish that the subject-matter claimed in the patent in suit is objectionable under Article 53(a) EPC, the Appellants rely inter alia on:
  - (i) a survey conducted among Swedish farmers on questions relating to genetic engineering and "super crops", according to which the large majority (82%) is against genetic engineering, and, in particular, against "super crops" (e.g. herbicide-resistant plants); and
  
  - (ii) an opinion poll carried out in Switzerland on the patentability of animals and plants, according to which the majority (69%) is opposed thereto.

They submit that both survey and opinion poll are probative of public opinion to the effect that patents should not be granted for these kinds of inventions. The Board does not agree with this conclusion. The results of surveys or opinion polls can scarcely be considered

decisive per se when assessing patentability of a given subject-matter with regard to the requirements of Article 53(a) EPC, for the following reasons:

- Surveys and opinion polls do not necessarily reflect "ordre public" concerns or moral norms that are deeply rooted in European culture.
- The results of surveys and opinion polls can fluctuate in an unforeseeable manner within short time periods and can be very easily influenced and controlled, depending on a number of factors, including the type of questions posed, the choice and the size of the representative sample, etc..
- Surveys of particular groups of people (e.g. farmers) tend to reflect their specific interests and/or their biased beliefs.
- As stated above, the question whether Article 53(a) EPC constitutes a bar to patentability is to be considered in each particular case on its merits. Consequently, if surveys and opinion polls were to be relied upon, they would have to be made ad hoc on the basis of specific questions in relation to the particular subject-matter claimed. For obvious reasons, such a procedure is scarcely feasible.
- Like national law(s) and regulation(s) approving or disapproving the exploitation of an invention (cf. point 7 supra), a survey or an opinion poll showing that a particular group of people or the majority of the population of some or all of the Contracting States opposes the granting of a patent for a specified subject-matter, cannot serve as a



sufficient criterion for establishing that the said subject-matter is contrary to "ordre public" or morality.

16. In essence, the Appellants submit that the exploitation of the claimed subject-matter (particular reference was made to the subject-matter of Claims 24 to 36 as granted) would damage the environment. This objection is raised with respect to both the issue of "ordre public", due to the alleged environmental consequences, and the issue of "morality", owing to concerns about the dominion gained by man over the natural world. These issues will be dealt with separately hereinafter by the Board taking into account the meaning of the concepts of "ordre public" and morality as previously defined (cf. points 5 to 7 supra).
  
17. With regard to the **morality** issue, the Board's considerations are as follows:
  - 17.1 The Appellants have expressed concerns about the dominion that was sought to be exercised by man over the natural world by the use of plant genetic engineering techniques. In this respect, it has to be considered that plant biotechnology is a technology which aims at accomplishing practical improvements or advances in the area of plants by using modern scientific knowledge. The development of this technology inevitably allows a better understanding and control of the natural phenomena linked to plants. However, in the Board's view, this does not render activities in this technical field intrinsically wrong. Indeed, in the Board's judgement, plant biotechnology per se cannot be regarded as being more contrary to morality than traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing

novel genetic material into it in order to obtain a new and, possibly, improved plant. However, compared with traditional breeding techniques, genetic engineering techniques applied to plants allow a more powerful and accurate control of genetic modifications. Plant biotechnology allows punctual gene modifications as well as the introduction into a given plant of genetic material from unrelated species of plants and from organisms other than plants. These techniques are an important tool to assist in plant breeding, which enables the performance of manipulations that would simply not be feasible by means of traditional breeding techniques. The impressive potential of these techniques is at the origin of the concerns and apprehensions expressed by public opinion and generates considerable disagreement and controversy. This factual situation forms the basis of the Appellants' objection to the dominion gained by man over the natural world. These concerns are understandable because the power of science for good and evil has always troubled man's mind. Like any other tool, plant genetic engineering techniques can be used for constructive or destructive purposes. It would undoubtedly be against "ordre public" or morality to propose a misuse or a destructive use of these techniques. Thus, under Article 53(a) EPC, no patent may be granted in respect of an invention directed to such a use. Consequently, it has to be established in the present case whether or not the claimed subject-matter relates to a misuse or to a destructive use of plant biotechnology.

- 17.2 The aim of the present invention is essentially to develop plants and seeds which are resistant to a particular class of herbicides, namely glutamine synthetase inhibitors (GSIs), and which are thereby selectively protected against weeds and fungal diseases. It should be noted that GSI-resistant plants or seeds

could also be obtained by traditional plant selection methods, since some plants may be naturally resistant or may develop such a resistance. The patent in suit discloses the use of modern biotechnological techniques for the production of GSI-resistant plants and seeds which contain, integrated into their genome in a stable manner, heterologous DNA encoding a protein capable of inactivating or neutralising the above-mentioned herbicides. In that way, a new trait is added to the genetic material of a plant of interest, which allows the plant to grow in the presence of GSIs.

- 17.3 In the Board's judgement, none of the claims of the patent in suit refer to subject-matter which relates to a misuse or destructive use of plant biotechnological techniques because they concern activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture. Alleged environmental consequences due to these activities will have to be considered against the background of the "ordre public" issue (cf. point 18 infra).
18. With regard to the issue of "**ordre public**", the Board, as already stated (cf. point 5 supra), takes the view that Article 53(a) EPC constitutes a bar to patentability for inventions the exploitation of which is likely to seriously prejudice the environment. Thus, careful consideration must be given to the objections and evidence put forward by the Appellants in this respect (cf. Section IX supra, item c).

- 18.1 Before going into a detailed examination of the specific points raised by the Appellants, some general remarks need to be made about the rights conferred by a patent on its owner(s) and the function of patent offices.
- 18.2 Patents are important instruments in the fields of technological research and development as well as of business strategy. A patent confers on its owner(s) for a specified time an exclusive right to exploit the subject-matter of the claims, i.e. to manufacture, use and market it, and to prevent others from doing the same. This protection is accorded in exchange of a full disclosure of the claimed invention. However, the right to exploit the invention is not unconditional. On the contrary, the invention claimed in a patent may only be exploited within the framework defined by national laws and regulations regarding the use of the said invention.
- 18.3 The function of a patent office is to grant patents, i.e. exclusive rights to make use of inventions claimed in said patents for a limited geographical area and for a specified time. The Board agrees with the Appellants' submission that patent offices are placed at the crossroads between science and public policy. However, at this crossroads patent offices are not alone, but find themselves side-by-side with an increasing number of other authorities and bodies, in particular regulatory authorities and bodies, whose function is inter alia to ensure that the exploitation of a given technology, **regardless of whether it is protected by a patent or not**, takes place within the regulatory framework provided by laws, international treaties, administrative provisions, etc. (cf., for example, the list of competent authorities responsible for the implementation of the EEC directive 90/220/EEC, Exhibit A submitted by the Respondents). The assessment

of the hazards stemming from the exploitation of a given technology is one of the important duties of such regulatory authorities and bodies.

- 18.4 In most cases, potential risks in relation to the exploitation of a given invention for which a patent has been granted cannot be anticipated merely on the basis of the disclosure of the invention in the patent specification. Typical examples are patents granted for chemical compounds with a pharmaceutical use. In this particular technical field, patents are generally granted on the basis of preliminary in vitro or animal data before any human clinical data become available. In fact, the actual approval (or disapproval) by the competent authorities of the exploitation of pharmaceutical products is often obtained only after the grant of the patent. This is because a realistic assessment of therapeutical operability requires a comprehensive and time-consuming programme of testing and evaluation of the products. The results of such tests are usually not available to patent offices during the prosecution of a case. During this time, the exploitation of the claimed products is most likely to be in the initial phase when risk and safety assessment by the competent authorities or bodies has either not yet taken place or not yet been completed. The same holds true for many other products the exploitation of which is subject to approval by the competent authorities or bodies, such as herbicides, insecticides, etc.. These specialised authorities and bodies are in a position to carry out a realistic assessment of risks or even hazards on the basis of the regulations in force, of objective criteria and of scientifically valid parameters. Also transgenic plants normally require regulatory approval in the majority of the countries where biotechnological developments are taking place

before even initial small-scale field testing can be performed (cf. e.g. EEC Directives 90/219/EEC and 90/220/EEC).

18.5 In the Board's judgement, the revocation of a European patent under Article 53(a) EPC on the grounds that the exploitation of the invention for which the patent has been granted would seriously prejudice the environment presupposes that the threat to the environment be sufficiently substantiated at the time the decision to revoke the patent is taken by the EPO. This view is consistent with the requirement that the exceptions to patentability under Article 53(a) EPC have to be narrowly construed, irrespective of whether or not the exploitation of the invention for which a European patent has been granted is prohibited by law(s) or regulation(s) in some or all of the Contracting States (cf. points 7 and 8 supra).

18.6 In the present case, no conclusive evidence has been presented by the Appellants showing that the exploitation of the claimed subject-matter is likely to seriously prejudice the environment. In fact, most of the Appellants' arguments are based on the **possibility** that some undesired, destructive events (e.g. the transformation of crops into weeds, spreading of the herbicide-resistance gene to other plants, damage to the ecosystem) might occur. Of course, such events may occur to some extent. This fact has even been admitted by the Respondents. However, in the Board's judgement, the documentary evidence submitted on this subject is not sufficient to substantiate the existence of a threat to the environment such as to represent a bar to patentability under Article 53(a) EPC. In particular:

- **Beaumont** (op.cit.) refers to the **potential** of GSIs to induce resistance in weed population and further states at the same time that "no reports have yet been received of resistance occurring" (see page 6). Reference is also made to **the possibility** of transmission of the herbicide-resistance gene to weed relatives of the crop and to **the possibility** of leaching of GSIs to water. Furthermore, the statement is made that there is "no convincing or reliable evidence to support the view that the introduction of herbicide-resistant crops will lead to a decrease in the amount of herbicide used and **it may well result in an increase**" (emphasis added). As a conclusion, **Beaumont** emphasizes the urgency of issuing an internationally agreed regulatory framework for the release, safe use and monitoring and enforcement of genetically modified organisms, including herbicide-resistant crops.
- **Fitter** (op.cit.) deals with the **probability** of turning a crop into a weed from a **theoretical** point of view.
- **Williamson I** (op.cit.) states that the development of herbicide-resistant crop plants **may give rise to some hazards** that are not easily quantified and that the engineered genes **may spread**. It concludes that it is the task of the Advisory Committee on Genetic Manipulation Intentional Introduction Subcommittee to assess and advise on the hazards of introducing into the environment genetically-engineered organisms of all kinds.
- **Williamson II** (op.cit.) discusses in general the **potential effects** of recombinant DNA organisms on ecosystems and their components and states that the risk of damage will be small, but the damage that

could be caused would be large. Indications are given on how to minimise the risks and the need for case-by-case examination of the risks is emphasized.

- **Le Baron** (op.cit.), while emphasizing the importance of herbicides in their potential inter alia for overcoming crop losses due to weeds, suggests that biotechnology research aimed at developing herbicide-resistant crops should, in particular, be aimed at developing major crops resistant to many herbicides, rather than one or two, in order to provide more flexibility in the control of resistant weeds.
- The article by J. Gressel in *Agro Food Industry Hi-Tech*, November/December 1992, pages 3 to 7 (hereinafter **Gressel**) referred to by the Respondents (cf. Exhibit C), while drawing the reader's attention to the possible risks linked to the misuse of genetic engineering in the creation of herbicide-resistant crops, emphasizes also the benefits which could be gained from such technology.

18.7 These documents provide fundamental evidence of **possible** hazards from the application of genetic engineering techniques to plants, in particular regarding the production of herbicide-resistant plants. This is done in order to increase the readers' awareness of the need to exploit this technology with caution. On the one hand, scientists are invited to minimise the risks by applying sensible design to experiments. On the other hand, administrators, in particular regulatory authorities and bodies, are invited to carry out their task of trying to detect even rare hazards and to assess all the risks involved in the exploitation of this



technology. The Board observes that the mere fact that, as deplored by **Beaumont** (op.cit), there may be inadequacies in the existing regulatory framework does not vest the EPO with authority to carry out tasks which should properly be the duty of a special regulatory authority or body constituted to that effect. However, in the Board's view, the quoted documents do not lead to the definite conclusion that the exploitation of any of the claimed subject-matter would seriously prejudice the environment and is, therefore, contrary to "ordre public". It would be unjustified to deny a patent under Article 53(a) EPC merely on the basis of **possible, not yet conclusively-documented hazards**. As already pointed out (cf. points 18.2 and 18.3 supra), a patent does not amount per se to an authorisation to exploit the invention claimed in the patent. For the latter regulatory approval must be obtained. Should the competent authorities and bodies, after having definitively assessed the risks involved, prohibit the exploitation of the invention, the patented subject-matter could not be exploited anyhow. If, however, regulatory approval is given based on the finding that no risks or minimal risks are involved, then patent protection should be available.

- 18.8 In the present case, since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to Article 53(a) EPC may not be based on the so-called "balancing exercise" of benefits and disadvantages, as submitted by the Appellants. The Board observes that such a "balancing exercise" is not the only way of assessing patentability with regard to Article 53(a) EPC, but just one possible way, perhaps useful in situations in which an actual damage and/or disadvantage (e.g. suffering of animals as in the case of decision T 19/90 supra) exists.

19. To sum up, the Board is of the opinion that, in the present case, Article 53(a) EPC does not constitute a bar to patentability because none of the claims of the patent in suit comprises subject-matter the exploitation of which would be contrary to "ordre public" or morality within the meaning of that article.

*The concept of "plant varieties" under Article 53(b) EPC*

20. Article 53(b) EPC, first half-sentence, excludes "plant varieties" from patentability. Decisions T 49/83 and T 320/87 (supra) were already concerned with the exclusion from patentability of "plant varieties" under this provision. Both decisions took into consideration the legal history of Article 53(b) EPC as well as the definition given to the concept of "plant varieties" in the UPOV Convention.
21. According to decision T 49/83 (supra), the concept of "plant varieties" stands for "a multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle", as reflected in the then valid UPOV Convention, and, thus, covers "all cultivated varieties, clones, lines, strains and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties, sufficiently homogeneous, and stable in their essential characteristics..." (cf. point 2 of the Reasons). The then competent Board held that "the legislator did not wish to afford patent protection under the European Patent Convention to plant varieties of this kind, whether in the form of propagating material or of the plant itself" and concluded that "Article 53(b) EPC prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety" (cf. point 3 of the Reasons). It was

further stated that "the very wording of Article 53(b) EPC before the semi-colon precludes the equation of plants and plant varieties..." (cf. point 4 of the Reasons). The claims underlying decision T 49/83 (supra) were directed to propagating material (seeds) of cultivated plants treated with an oxime derivative. It was held that the claimed innovation did not lie within the sphere of plant breeding, which was concerned with the genetic modification of plants. The parameter "treated with an oxime derivative" was not considered to be a criterion characteristic of a plant variety because the treatment could also be carried out on propagating material which did not meet the essential criteria of homogeneity or stability characteristic of a plant variety. Thus, Article 53(b) EPC was not considered an obstacle to the patenting of the claimed propagating material.

22. Decision T 320/87 (supra) confirmed the findings of T 49/83 (supra) in respect of the significance of the exclusion from patentability of "plant varieties" under Article 53(b) EPC. The claims underlying decision T 320/87 were directed to hybrid seeds or plants which were not stable and thus could not be defined as "varieties". In fact, the invention relied on going back repeatedly to the parent plants for further propagation by cloning because the hybrids resulting from the crossing of the parent plants, one of which was heterozygous, did not provide plants, which, when further sexually propagated, remained stable with respect to the desired features. The then competent Board expressed the view that single individual plants were not to be so construed as being embraced within the subject-matter of the product claim. For these reasons, it was decided that the exception to patentability under Article 53(b) EPC did not apply to the claimed subject-matter.

23. Thus, in the Board's judgement, the concept of "plant varieties" under Article 53(b) EPC, first half-sentence, refers to any **plant grouping** within a single botanical taxon of the lowest-known rank which, irrespective of whether it would be eligible for protection under the UPOV Convention, is characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics (cf. points 21 and 22 supra; Article 1, item (vi) of the revised UPOV Convention, Geneva 1991). **Plant cells** as such, which modern technology allows to culture much like bacteria and yeasts, cannot be considered to fall under the definition of a plant or of a plant variety. In this respect, it is further noted that plant cells are considered to be "microbiological products" in the broad sense under the current practice of the EPO (cf. points 34 and 35 infra).
24. A product claim which embraces within its subject-matter "plant varieties" as just defined (cf. point 23 supra) is not patentable under Article 53(b) EPC, first half-sentence (cf. point 20 supra).

*The concept of "essentially biological processes for the production of plants" under Article 53(b) EPC*

25. Article 53(b) EPC further excludes "essentially biological processes for the production of plants..." from patentability. The historical documentation shows that, when drafting Article 53(b) EPC, the EPC Working Party recognised that even if protection of new plant varieties and processes for producing new plants was to be excluded under European patent law, European patents still had to be granted for processes which, while applicable to plants, were of a technical nature (cf. document IV/2071/61-E, page 6, first paragraph).

Processes for producing new plants by irradiation of the plants themselves or the seed with isotopes were cited as an example of such processes (ibid., loc.cit.). The Board observes that the example given is one in which plants or seeds undergo genetic modifications due to irradiation.

26. In order to provide a distinction between **inventions resulting from non-technical processes for the production of plants** (e.g. essentially biological processes such as selective breeding), which were to be excluded, and **inventions resulting from technical processes for the production of plants**, which were considered patentable, the legislator introduced in Article 53(b) EPC, first half-sentence, the exclusion from patentability of "essentially biological processes for the production of plants...". As is derivable from the example given in the quoted document of the EPC Working Party (cf. point 25 supra), this provision gives rise to the legal consequence that processes of a technical nature for producing plants, including processes involving genetic modification of plants, are patentable. By virtue of Article 64(2) EPC, the protection conferred by a European patent to a process extends also to the products (e.g. plants) directly obtained by such a process.

27. As regards the interpretation of the concept of "essentially biological processes for the production of plants...", it is pointed out in decision T 320/87 (supra) that whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC "has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved" (cf. point 6 of the Reasons). The then competent Board considered that

the claimed processes for the preparation of hybrid plants represented an essential modification of known biological and classical breeders' processes which had a decisive impact on the desired resulting hybrid population. Accordingly, it was held that the said processes could not be considered "essentially biological" within the meaning of Article 53(b) EPC and that, therefore, the exclusion from patentability did not apply.

28. Based on the above considerations, it follows that a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result (cf. points 25 to 27 supra), does not fall under the exceptions to patentability under Article 53(b) EPC, first half-sentence.

*The concepts of "microbiological processes" and "the products thereof" under Article 53(b) EPC*

29. Finally, Article 53(b) EPC, in its second half-sentence, disposes that the provision under Article 53(b) EPC, first half-sentence, concerning exceptions to patentability "does not apply to microbiological processes or the products thereof". In the light of the historical documentation, the inclusion of a specific exception to said provision for microbiological processes or the products thereof may be explained by the legislator's intention to make it absolutely clear that the EPC must provide patent protection for industrially applicable processes involving microorganisms and for their products. This clarification was most certainly considered useful in order to prevent the exclusion from patentability from being extended to processes using eucaryotic

microorganisms which could be fitted into the pattern of the plant or animal kingdoms (e.g. some fungi, plant cells, animal cells).

30. In decision T 19/90 (supra, cf. point 4.10 of the Reasons), it is pointed out that the second half-sentence of Article 53(b) EPC is an exception to the exception to patentability provided for by the first half-sentence of this provision. Accordingly, it is held that the second half-sentence restores the general principle of patentability laid down in Article 52(1) EPC for inventions involving microbiological processes and the products thereof. Thus, from this decision it follows that animal varieties are patentable if they are the product of a microbiological process within the meaning of Article 53(b) EPC, second half-sentence. In the Board's judgement, this principle applies *mutatis mutandis* to plant varieties.

31. The Board observes that the EPC does not provide a definition of the concepts of "microbiological processes" and "the products thereof". Nor can a definition of these concepts or any relevant indication in this respect be found in the historical documentation relating to the EPC. As a matter of fact, the EPC Working Party stated that "it seemed preferable to leave the question...to the courts without laying down any express rules since there was a risk of any express rule distorting the sense of the provision by introducing an *contrario* argument" (cf. document 6551/IV/62-E, pages 7 and 8). Different views have been expressed in this context by the parties to the present appeal proceedings:

- the Appellants maintained that a literal interpretation had to be given to the concepts in question. In their submissions, the second half-

sentence of Article 53(b) EPC was limited to processes (e.g. production of antibiotics by fermentation) involving microorganisms in the traditional sense, i.e. bacteria, yeasts and the like. Consequently, in the Appellants' view, the concept "microbiological" should not be construed as meaning "technical".

- The Respondents submitted that a technical process involving a microbiological step acquired a microbiological character and, consequently, its products had to be regarded as products of a microbiological process.

Both viewpoints find support in the specialised literature (among the many possible citations, cf., for example, R. Lukes in GRUR Int., 1987, Vol.5, pages 318 to 329, in support of the Appellant's view, and F. K. Beier et al in BIOTECHNOLOGIE ET PROTECTION PAR BREVET, Une analyse internationale, 1985, in particular page 75, in support of the Respondents' view).

32. The Board is satisfied that the proper course of action, in view of the recent important developments in the field of microbiology, is to interpret Article 53(b) EPC, second half-sentence, according to objective teleological criteria and that this way of interpreting is consistent with the legislative intent underlying this provision. Among these criteria, the principle of equal treatment of what is of the same kind or similar is of great importance. Such interpretation may give rise to subject-matter being regulated by this provision which could not possibly have been anticipated by the historical legislator.



33. Traditional microbiology was primarily concerned with the production, by means of fermentation processes, of primary and secondary metabolites (e.g. acetic acid or antibiotics), and with biotransformations (production of biomass, enzymatic reactions). Modern microbiology combines the traditional techniques with the genetic engineering techniques and makes use of experimental approaches which are widely applicable to human, animal and plant cells that can be maintained and grown in culture much like bacteria and yeasts.
34. According to the current practice of the EPO, the term "**microorganism**" includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition (cf. Guidelines for Examination, C-IV, 3.5). This practice is consistent with the objective teleological interpretation of Article 53(b) EPC, second half-sentence, in particular with the principle of equal treatment (cf. paragraph 32 supra), and is, therefore, fully acceptable. Furthermore, this practice takes clearly into account the developments of modern industrial microbiology (cf., for example, A. Kocková-Kratochvilová, "Characteristics of Industrial Microorganisms", in "Biotechnology", 1981, Vol.1, H.-J. Rehm and G. Reed eds., Verlag Chemie, Weinheim, Chapter 1, pages 5 to 71, in particular page 7), fulfilling thereby an objective purpose of Article 53(b) EPC, second half-sentence.
35. Accordingly, the term "**microbiological**" is interpreted as qualifying technical activities in which direct use is made of microorganisms as defined above (cf. point 34 supra). These include not only traditional fermentation

and biotransformation processes, but also the manipulation of microorganisms by genetic engineering or fusion techniques, the production or modification of products in recombinant systems, etc., i.e., briefly, all activities in which an integrated use is made of biochemical and microbiological techniques, including genetic and chemical engineering techniques, in order to exploit the capacities of microbes and cultured cells [cf., for example, H.-J. Rehm and G. Reed, "Introduction" in "Biotechnology", op.cit. Chapter 0 (sic), pages 1 to 3]. Therefore, as an example, genetic engineering processes carried out on vegetable cells may be defined as "microbiological processes" and their products, namely genetically-modified vegetable cells and their cultures, may be defined as "the products thereof".

36. In the Board's judgement, the concept of "**microbiological processes**" under Article 53(b) EPC, second half-sentence, refers to processes in which microorganisms as defined above (cf. point 34 supra), or their parts, are used to make or to modify products or in which new microorganisms are developed for specific uses. Consequently, the concept of "**the products thereof**" under Article 53(b) EPC, second half-sentence, encompasses products which are made or modified by microorganisms as well as new microorganisms as such.
37. As modern biotechnology often uses or develops multi-step processes for producing plants which include at least one microbiological process step (e.g. the transformation of cells with recombinant DNA), it has to be decided whether such processes as a whole can be considered to represent "microbiological processes" within the meaning of Article 53(b) EPC, second half-sentence, and whether, owing to this, the products of

such processes (e.g. plants) may be regarded as being "the products thereof" for the purposes of this provision.

38. In the Board's judgement, microbiological processes as defined above (cf. points 35 and 36 supra) and technical processes comprising a succession of steps, wherein at least one essential step is of a microbiological nature, may not be considered to be of the same kind or similar so that the principle of equal treatment would apply with respect thereto (cf. point 32 supra). Consequently, the concept of "microbiological processes" under Article 53(b) EPC, second half-sentence, interpreted according to objective teleological criteria (cf. point 32 supra), may not be extended to include all the steps of such technical processes. Neither are there scientific reasons to include them. Furthermore, the second half-sentence of Article 53(b) EPC refers merely to "microbiological processes", and **not** to "**essentially** microbiological processes". In the Board's view, this indicates that the historical legislator did not want the concept of "microbiological processes" under Article 53(b) EPC, second half-sentence, to be extended to include such technical processes either. Besides, in principle, Article 53(b) EPC, first half-sentence, does not exclude from patentability modern multi-step processes for producing plants involving genetic engineering techniques. In fact, whenever such processes are shown to be of a technical nature, they are patentable under the EPC without limitation. In the Board's opinion, had the historical legislator been aware of such processes, it would have considered them to be further examples of **technical** processes applicable in particular to plants for which European patents had to be granted (cf. document IV/2071/61-E, loc.cit.; point 25 supra).

39. In conclusion, the Board is of the opinion that "technical processes including a microbiological step" may not simply be equated with "microbiological processes". Nor can the resulting final products of such technical processes (e.g. plant varieties) be defined as "products of microbiological processes" within the meaning of Article 53(b) EPC, second half-sentence (cf. points 23, 35 and 36 supra, and point 40.9 infra).

*Assessment of patentability with regard to the requirements of Article 53(b) EPC.*

40. The examination of the main request (Claims 1 to 44 as granted) gives rise to the following considerations:
- 40.1 As regards the process according to Claim 7, the Board cannot share the Appellants' view that, notwithstanding the human, technical intervention in the first step of the process in which, as a random event, plant cells or tissue are transformed with a recombinant DNA, the subsequent steps of regenerating and replicating the plants or seeds confer an overall biological character on the process and that, regarding the subject-matter of this claim, the exclusion from patentability under Article 53(b) EPC, first half-sentence, should therefore apply. On the contrary, Claim 7 does not relate to a process which is "essentially biological" within the meaning of this provision (cf. points 27 and 28 supra) because the step of transforming the plant cells or tissue with a recombinant DNA, regardless of whether its performance is dependent on chance or not, is an essential technical step which has a decisive impact on the desired final result. If it is not successfully performed, plants or seeds could most probably still be regenerated from the plant cells or tissue and they could replicate, but they would not display the desired distinctive characteristic of having the heterologous

DNA integrated in their genome in a stable manner. Therefore, although the subsequent steps of regenerating and replicating the plants or seeds make use of the "natural" machinery, the decisive step, namely the insertion of the relevant DNA sequence into the genome of the plant, could not occur without human intervention. In this respect, it is also noted that the regeneration step is not entirely biological, but rather agrotechnical, since some degree of technical intervention is required in the selection of the proper working conditions. Therefore, the process of Claim 7 as a whole is not "essentially biological" and, thus, not excluded from patentability under Article 53(b) EPC, first half-sentence.

40.2 As for Claim 14, which relates to plant cells, the Board cannot agree with the Appellants' submission that this claim covers de facto plant varieties and that, for this reason, it is not allowable under Article 53(b) EPC, because, as already stated (cf. point 23 supra), plant cells as such may not be considered to fall under the definition of a plant or plant variety. Thus, the subject-matter of Claim 14 does not represent an exception to patentability under Article 53(b) EPC.

40.3 As regards Claim 21, it is noted that this claim is not drafted in terms of a variety description because there is no reference to a single botanical taxon of the lowest-known rank (cf. point 23 supra). Rather this claim is in general directed to a plant which possesses, integrated in its genome in a stable manner, a heterologous DNA containing a foreign nucleotide sequence encoding a protein having a non-variety specific enzymatic activity capable of neutralising or inactivating a glutamine synthetase inhibitor under the control of a promoter recognised by the polymerases of the plant cells. The reference to a "non-variety

specific" enzymatic activity intends to emphasize that it is not characteristic of specific plant genes or species (cf. specification of the patent in suit page 8, lines 14 to 16).

- 40.4 The subject-matter of Claim 21 differs decisively from the subject-matter dealt with in decisions T 49/83 and T 320/87 (cf. points 21 and 22 supra) in that it relates to genetically modified plants which remain stable in their modified characteristic(s). The stated characterising feature of the claimed plant is, in fact, transmitted in a stable manner in the plants and seeds throughout succeeding generations (cf. specification of the patent in suit, page 7, lines 59 to 61). The working examples in the patent in suit relate to the production of transformed plants from known varieties (e.g. *Nicotiana tabacum* cv. Petit Havana SR1, *Solanum tuberosum* cv. Berolina or cv. Désirée, *Lycopersicon esculentum* cv. Lucullus). It is shown with tobacco plants that the plants transformed in this way display normal fertility and that the second generation seedlings are homozygous for the resistance gene. Thus, the transformed plants or seeds of the working examples, irrespective of whether they would meet the conditions for the grant of a breeder's right, are plant varieties as they comply with the definition of the concept of "plant varieties" (cf. points 21 to 23 supra), being distinguishable, uniform and stable in their relevant characteristics. As a matter of fact, these exemplified varieties may be construed as "essentially derived varieties", being obtained from known varieties by transformation by genetic engineering techniques [cf. Article 14(5), in particular item (c) of the revised UPOV Convention, Geneva 1991].

40.5 Claim 21 defines plants which, regardless of whether or not they belong to any particular variety, are distinguished from all other plants by the stated specific characteristic which is transmitted in a stable manner to the progeny. While Claim 21 defines the distinctive feature common to all plants covered by this claim, the working examples of the patent in suit show that the practical forms of realisation of the invention according to Claim 21 are "genetically transformed" plant varieties. Consequently, the subject-matter of Claim 21 encompasses genetically transformed plant varieties showing said single distinctive feature, even though this claim is not drafted in terms of a variety description. This reasoning is in keeping with the general principle laid down in the established practice of the Boards of Appeal, according to which the provision in Article 69(1) EPC, stipulating that the description and drawings (if any) be used to interpret the claims, also applies when an objective assessment of the content of a claim has to be made (cf. T 16/87, OJ EPO 1992, 212; T 544/89 of 27 June 1991 and T 565/89 of 26 September 1990, not published in the OJ EPO).

40.6 The Respondents admit that the said working examples were carried out on existing varieties. Moreover, they do not deny that Claim 21 encompasses also plant varieties. Since the Respondents cannot see any possibility of introducing an appropriate disclaimer, they submit that finding a specific plant variety which falls under Claim 21 may be compared to a selection invention in chemistry, the specific plant variety representing a selection among the broad class of plants claimed. The Board cannot accept this submission because plant varieties, regardless of whether or not they may represent a selection invention, are excluded from

patentability by virtue of Article 53(b) EPC, first half-sentence, unless the exception under Article 53(b) EPC, second half-sentence, applies.

40.7 A claim is not allowable if the grant of a patent in respect of the invention defined in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability. Accordingly, it has, for example, already been decided that a claim falls under the prohibition of Article 52(4) EPC if the invention claimed therein is not solely directed to a cosmetic effect, but is also necessarily defining a treatment of the human body by therapy (cf. T 290/86, OJ EPO 1992, 414).

40.8 Given the fact that Claim 21 encompasses plant varieties (cf. point 40.5 supra), it follows, therefore, that Claim 21 is only allowable, if the exception to patentability under Article 53(b) EPC, first half-sentence, concerning plant varieties does not apply, because the subject-matter of this claim is to be regarded as the product of a microbiological process (cf. points 30 and 40.6 supra).

40.9 The plant according to Claim 21 is produced by a multi-step process (cf. process according to Claim 7) which, in addition to the initial microbiological process step of transforming plant cells or tissue with recombinant DNA, comprises the step of regenerating plants from the transformed plant cells or tissue and the step of reproducing the plant material. The initial microbiological process step undeniably has a decisive impact on the final result because by virtue of this step the plant acquires its characterising feature that is transmitted throughout generations (cf. point 40.4 supra). However, the Board observes that the subsequent steps of regenerating and reproducing the plants have an



important added value and contribute, although in a different manner, to the final result as well. These two process steps involve complex phenomena and events such as cell differentiation, morphogenesis and reproduction and may, therefore, not be equated to the much simpler process step of multiplying and propagating transformed plant cells or tissue in culture, which is a typical microbiological process. In fact, in a cell or tissue culture process plant cells proliferate in a rather disorganised manner either in suspension or by producing a mass of relatively undifferentiated cells which all look much alike (callus). In contrast to that, a process of regenerating a whole plant from plant cells or tissue, which takes advantage of the totipotency of many plant cells, comprises a series of important events and phases, such as the formation of shoot and then root meristems, the coordinated division, expansion and differentiation of cells, which require the careful selection of the appropriate working conditions, e.g. the manipulation of nutrients and growth regulators. Furthermore, a subsequent biological process step of replicating the regenerated plant involves a further series of relevant phenomena and events such as fertilisation, germination, growth and development. It is the controlled performance and/or successful occurrence of all these phases and events which will then allow the "imprinted" plant cells or tissue to develop into a whole plant. Such a plant is not identical to the initial starting product (the transformed plant cells or tissue) in spite of the fact that it contains the same characterising genetic information. A whole plant cannot be assimilated to a plant cell or tissue for the sole reason that it has acquired its characterising feature during the initial "microbiological" step of transforming the plant cell or tissue. The plant according to Claim 21 is thus not

merely the result of said initial step, but also of the subsequent series of relevant agrotechnical and biological steps.

40.10 It ensues that, regardless of the decisive impact that the microbiological process step has on the final result, the multi-step process whereby the plant according to Claim 21 is produced is not a microbiological process within the meaning of Article 53(b) EPC, second half-sentence, (cf. points 38 and 39 supra). Accordingly, such a plant may not be considered to be "the product of a microbiological process".

40.11 This means that the exception to patentability under Article 53(b) EPC, first half-sentence, concerning plant varieties does apply in respect of the invention as defined in Claim 21. Consequently, Claim 21, which encompasses plant varieties, is not allowable (cf. points 40.5 to 40.8 supra). Thus, the main request, of which Claim 21 is part, has to be rejected.

40.12 These conclusions are not at variance with decision T 19/90 (cf. point 30 supra) whereby the then competent Board, while laying down the principle that patents are grantable for animal varieties produced by a microbiological process, remitted the case to the Examining Division for further consideration of its merits in this respect (cf. point 4.10 of the Reasons, last sentence).

41. Claim 23 of the first auxiliary request is drafted as a "product-by-process" claim and is directed to plants obtained by the process according to Claims 7 to 13. The mere fact of using a different wording in comparison with Claim 21 of the main request does not alter the actual subject-matter claimed. Therefore, plant

varieties are not excluded from the scope of Claim 23 (cf. point 40.5 supra). Thus, Claim 23 is not allowable for the same reasons given with respect to Claim 21 of the main request (cf. points 40.7 to 40.11 supra) and the first auxiliary request, of which Claim 23 is part, has to be rejected as well.

42. Claim 20 of the second auxiliary request, which is drawn up as a claim dependent upon Claims 14 to 17, is directed to plant cells "which are contained in a plant". It is noted that plant cells contained in a plant are differentiated cells which are morphologically and functionally organised to constitute the plant. In the Board's judgement, this is the inevitable understanding of the skilled person. Consequently, the dependency of Claim 20 upon Claim 14 is rather misleading, because the latter claim is in general directed to transformed plant cells. Thus, the subject-matter of Claim 20, irrespective of the way the latter is drafted, is nothing but a plant, and this claim does not exclude from its scope plant varieties for the same reasons as Claim 21 of the main request (cf. point 40.5 supra). Furthermore, like the plants according to Claim 21 of the main request, such plants may not be considered to be the product of a microbiological process (cf. points 40.9 to 40.11 supra). Thus, Claim 20 is not allowable for the same reasons given with respect to Claim 21 of the main request (cf. points 40.7 to 40.11 supra), and the second auxiliary request, of which Claim 20 is part, has equally to be rejected.

43. The examination of the third auxiliary request gives rise to the following considerations: As it can be seen above (cf. Section VIII supra), Claims 1 to 38 of this request differ from the claims as granted in that Claims 18 to 23 (seeds and plants) have been deleted, all remaining claims being either unchanged (Claims 1 to

17) or correspondingly amended and renumbered (Claims 18 to 38). As already discussed above (cf. points 40.1 and 40.2 supra), Claim 7 and Claim 14 of this request are not excluded from patentability under the provisions of Article 53(b) EPC. As for the remaining claims, none of them relate to subject-matter which falls under the exclusion from patentability of that article.

*Conclusion*

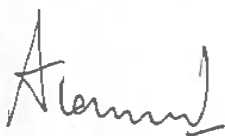
44. Neither paragraph (a) nor paragraph (b) of Article 53 EPC constitute a bar to the patentability of Claims 1 to 38 of the third auxiliary request. As no other substantive objections have been raised, the patent in suit can be maintained in amended form on the basis of this request.

**Order**

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

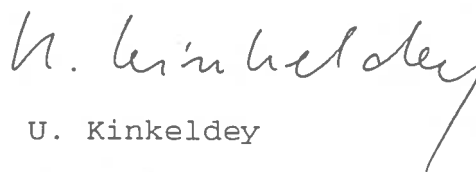
1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of Claims 1 to 38 according to the third auxiliary request submitted during oral proceedings.

The Registrar:



A. Townsend

The Chairwoman:



U. Kinkeldey

