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DECISIONS OF THE ENLARGED BOARDS OF APPEAL

Decision of the Enlarged Board of Appeal dated 20 December 1999

G 1/98

(Language of the proceedings)

Composition of the board:

Chairman: P. Messerli

Members: R. Teschemacher

G. Davies

B. Jestaedt

P. Lançon

J.-C. Saisset

P. van den Berg

Applicant: Novartis AG

Headword: Transgenic plant/NOVARTIS II

Article: 52, 53(b), 54, 64(2) EPC

Rule: 23b EPC

Strasbourg Patent Convention Art. 2(b)

UPOV Convention 1961 Art. 2

UPOV Convention 1991 Art. 1(vi)

Keyword: "Claims comprising but not identifying plant varieties" - "Plant varieties as products of recombinant gene technology" - "Article 64(2) EPC not relevant for examination of product claims"

Headnote

I. A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties.

II. When a claim to a process for the production of a plant variety is examined, Article 64(2) EPC is not to be taken into consideration.

III. The exception to patentability in Article 53(b), first half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.

Summary of facts and submissions

I. In its decision T 1054/96 (Transgenic plant/NOVARTIS, OJ EPO 1998, 511), Technical Board of Appeal 3.3.4 referred the following points of law to the Enlarged Board of Appeal under Article 112(1)(a) EPC:

1. To what extent should the instances of the EPO examine an application in respect of whether the claims are allowable in view of the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof, and how should a claim be interpreted for this purpose?

2. Does a claim which relates to plants but wherein specific plant varieties are not individually claimed ipso facto avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?

3. Should the provisions of Article 64(2) EPC be taken into account when considering what claims are allowable?

4. Does a plant variety, in which each individual plant of that variety contains at least one specific gene introduced into an ancestral plant by recombinant gene technology, fall outside the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof?

II. The application in suit before the referring Board relates to the control of plant pathogens in agricultural crops. It contains claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which results in the production of antipathogenically active substances, and to methods of preparing such plants. The plants according to the invention are able to kill or inhibit the growth of pathogens. The referring Board considers the above questions relevant to any assessment of the patentability of the claims.

III. In so far as they are relevant to this decision, the considerations of the referring Board may be summarised as follows:

Product claims to plants

The product claims of the application in suit covered plants which might or might not belong to a plant variety. In examining a claim for the purpose of Article 53(b) EPC, the claim had to be construed in the same way as when considering novelty or inventive step. The normal principle for these latter purposes was that a patent was granted for everything falling within the scope of the claim. If a claim also covered varieties, then the patent was granted also for varieties. In so far as a potential embodiment was a variety, it was not patentable.

Board 3.3.4 could not accept the appellant's argument that a claim comprising more than a single variety was permissible. It did not appear to the Board to comply with the normal rules of logic. If the argument were accepted, the prohibition of Article 53(b) EPC could be avoided by drafting a claim to a plant with some characteristics of any actual embodiment left unspecified. The concept that specific embodiments of an invention, namely the actual plant varieties, should not be patentable, but that it should be possible to have a broad claim to plants, the scope of which would include all such varieties, was a notion quite alien to patent law in general. It would leave a fundamental anomaly at the heart of patent law as it related to plants.

The legislative history suggested that all problems posed by the patenting of self-reproducing living organisms at the level of higher plants or animals were simply to be by-passed by excluding them from patentability under the EPC. At the time the Strasbourg Patent Convention and the EPC were drafted, it was inconceivable that varieties could be obtained with the help of techniques including microbiological steps. Thus, the legislator could not have intended that plant varieties should be patentable as products of microbiological processes. A genetically-engineered plant variety bore no relation to what was originally meant by the product of a microbiological process, whereas it was virtually indistinguishable in type from conventionally-produced plant varieties. The prohibition in Article 53(b) EPC rather suggested an intention to exclude plant varieties from protection until such time as the legislator reconsidered the matter. Comparing the provisions of Article 52(2) and Article 53(b) EPC, the Board considered that only the latter exclusion concerned developments falling into the legal category of inventions. The case law of the Boards of Appeal in cases relating to Article 52(2) EPC did not offer a useful analogy to the legal status of plant varieties. It concerned situations where subject-matter excluded only "as such" under Article 52(3) EPC was used as part of a combination, which as a whole could be considered to be an invention. Rather, the case law relating to Article 52(4) EPC was considered relevant which found methods, although not expressly directed to a method of treatment of the human body, unpatentable for the very reason that they could also serve as therapeutic methods of treatment

of the human body which were excluded from patentability. Even if one essential historical reason for the exclusion of plant varieties was the prohibition of double protection in Article 2(1) of the International Convention for the Protection of New Varieties of Plants (UPOV Convention), this did not necessarily lead to the conclusion that in the application of Article 53(b) EPC its plain wording was to be disregarded.

The mere fact that a plant variety was obtained by means of genetic engineering was no reason to give the producer of such a variety a privileged position. Granting patents for new types of plants developed since Article 53(b) EPC was enacted, in order to meet the interests of the inventors active in this new field, was a matter for a revision conference of the Contracting States, since it would extend the scope of the EPC beyond that originally agreed. Furthermore, it appeared to be inconsistent with subsequent practice as illustrated by the UPOV Convention 1991 and the Community Regulation on Community Plant Variety Rights, both of which provided for the protection of plant varieties produced by genetic engineering. From the draft EC Biotechnology Directive it could be understood that, in all cases where a concept of genetic engineering applicable to more than one variety was the invention, the resulting products should be patentable, even if they were plant varieties. This would lead to the conclusion that the appellant's "more than one variety approach" would be most compatible with the draft Directive. On the other hand, it could also be considered that the draft Directive would be satisfied by permitting claims to the process resulting in the plant.

Claims for essentially biological processes

With regard to the question whether a process can be defined as an essentially biological process excluded under Article 53(b), first half-sentence, EPC, the referring decision considers three approaches:

(a) By analogy with the case law applying to Article 52(4) EPC, only processes comprising exclusively non-biological process steps could be considered as non-essentially biological within the meaning of Article 53(b) EPC.

(b) In T 320/87, it was held that the decision had to be taken on the basis of the essence of the invention taking into account the totality of human intervention, and its impact on the results achieved. As discussed in T 356/93, this would have the consequence that a process containing at least one essential technical step, which could not be carried out without human intervention and which had a decisive impact on the final result, did not fall under the exclusion.

(c) To escape the prohibition of Article 53(b) EPC, the approach adopted in Article 2 No. 2 of the draft EC Biotechnology Directive would require at least one clearly identified non-biological process step but would allow any number of additional essentially biological steps.

The referring Board saw no conflict between, on the one hand, the plant variety indirectly enjoying patent protection under Article 64(2) EPC as the direct product of a patented process for the production of the variety and, on the other hand, the plant variety as such not being patentable under Article 53(b) EPC. Therefore, method claims for the manufacture of plants should not be examined as to their patentability in the light of Article 64(2) EPC.

IV. In conclusion, the position of Board 3.3.4 may be summarised as follows:

Question 1

Product claims:

Irrespective of the wording used in a claim, it was necessary to decide whether the claim was in whole or in part directed to subject-matter for which a patent should not be granted. The fact that plant varieties were covered by a claim could not be

ignored. For the purpose of Article 53(b) EPC, a claim was to be construed in the same way as when considering novelty and inventive step. If a potential embodiment was a plant variety, it was not patentable.

Essentially biological processes

The Board did not state a preference for any one of the three approaches outlined in the referring decision to deciding whether a process can be defined as an essentially biological process.

Microbiological processes and their products

Genetically engineered varieties were covered by the prohibition on granting patents for plant varieties under Article 53(b) EPC even if the variety should in some sense be considered the product of a microbiological process.

Question 2

According to the normal rules of logic, it could not be deduced from the plain wording of Article 53(b) EPC that a patent should not be granted for a single plant variety but might be granted if its claim covered more than one variety.

Question 3

Method claims for the manufacture of plants should not be examined as to their patentability in the light of Article 64(2) EPC, ie claims for the manufacture of plants by means of genetic engineering were allowable.

Question 4

Plant varieties obtained by means of genetic engineering did not fall outside the exclusion from patentability in Article 53(b) EPC.

V. The appellant in T 1054/96 suggested answering the questions posed as follows:

Question 1

The instances of the EPO were obliged to take into account relevant provisions of international conventions in their interpretation of the EPC, such as Article 53(b) EPC. Thus, the interpretation of the EPC needed to be brought into line with the terms of the EC Biotechnology Directive.

Question 2

A claim that did not specifically relate to plant varieties but to transgenic plants having certain features was allowable in the case of an invention the technical feasibility of which was not confined to a particular plant variety.

Question 3

Article 64(2) EPC should not be considered a bar to patentability when a claim was concerned that related to a method for the production of transgenic plants.

Question 4

The recombinant origin of a plant did not make any difference to the question whether or not a plant variety was excluded from patentability by Article 53(b) EPC.

VI. In support of its position, inter alia the appellant described the approach taken by the referring Board as an "infringement test", holding a claim as a whole not patentable if it covered an embodiment which was excluded from patentability by Article 53(b) EPC. Such an approach would contradict the practice of the EPO of granting claims which might encompass aesthetic creations explicitly excluded from patentability according to Article 52(2) EPC. Similarly, a claim to a gene would be

excluded under the Board's approach, if the protection extended to a plant variety carrying the gene as now specifically laid down in Article 9 of the EC Biotechnology Directive. In examining the examples in the description, the Board failed to examine whether the contribution to the art in the application as a whole was a true generic invention. If a technical teaching was applicable to plants in general and was not restricted to the provision of one specific plant variety, the applicant should be entitled to broad claims defining this technical contribution, regardless of whether these claims also embraced plant varieties. Sui generis protection for individual plant varieties could not give adequate protection for the broadly-applicable technical teaching. In its communication accompanying the summons to oral proceedings, Board 3.3.4 had mentioned the need to prevent discrimination against plant breeders: actually the Board had interpreted Article 53(b) EPC more narrowly than the interested plant breeders' groups ever had, discriminating against technical inventors whose teachings could be exploited by plant breeders without remuneration.

From a technical point of view, Board 3.3.4 was not correct in assuming that a stable insertion of a desired gene into an existing plant variety would lead to another variety which differed from the untransformed starting material only in the desired feature. After the stable integration of the introduced DNA into the genome, several steps of crossing and back-crossing were necessary to arrive at a homogeneous plant which might represent a variety.

In discussing the "more than a single variety" approach, the referring Board did not take due account of the meaning of the notion of plant variety for the relationship between patent protection and sui generis plant variety rights. As was evident from decision T 49/83, the crucial issue was whether a specific technical teaching could, in principle, be protected as subject-matter under the special plant varieties protection scheme. If yes, no protection was available under Article 53(b) EPC. If not, the teaching had to be viewed as subject-matter eligible for patent protection.

VII. The President of the EPO took the following position:

Question 1

Product claims

The term "plant variety" had to be ascertained by relying on definitions developed in the plant breeders' rights system. The subject-matter excluded by Article 53(b) EPC was the same as the subject-matter protectable under that system. A group of plants merely characterised by one or more single feature(s) fell short of qualifying as a plant variety. The exclusion of plant varieties should not be extended to cover other product inventions related to plants.

Essentially biological processes

A process for the production of plants was essentially biological if it consisted entirely of natural phenomena, these being understood as including the methods used by conventional plant breeders, such as crossing or selection.

Microbiological processes

A microbiological process for the production of plants was patentable.

Question 2

A claim which embraced plant varieties without claiming them individually did not fall under the exclusion in Article 53(b) EPC.

Question 3

Article 64(2) EPC should not be taken into account when considering what claims are allowable.

Question 4

Plant varieties were not patentable even if produced by a microbiological process, by modern genetic technology or by a process which was not essentially biological.

VIII. Many statements pursuant to Article 11b of the Rules of Procedure of the EBA were filed.

Statements in favour of the patentability of claims comprising transgenic plants were filed by professional groups in the industrial property field (*epi*, CIPA, Deutsche Vereinigung für gewerblichen Rechtsschutz und Urheberrecht [Fachausschuß für Pflanzenzüchtungen]), Industry Groups (UNICE, BioIndustry Association [UK], European Crop Protection Association), applicants active in the field of plant breeding (PGS, Monsanto) and attorneys.

In general, they stressed that Article 52(1) EPC expressed the general principle that patents should be granted for any inventions. Exceptions to this principle should be construed narrowly.

The wording of Article 53(b), first half-sentence, EPC allowed different interpretations. In interpreting the provision, its purpose and the intention of the legislator had to be taken into account. Apparently, the legislator did not intend to exclude plants in general, otherwise the term "plant varieties" would not have been used to define the field of exclusion. The provision was intended to implement the ban on double protection contained in the UPOV Convention 1961. However, it was not its purpose to exclude subject-matter not eligible for protection under the plant breeders' rights system. In particular, it could not have been the intention of the legislator to exclude transgenic plants from patentability since it was not technically feasible to produce such plants at the time the EPC was drafted. Therefore, the term plant varieties in Article 53(b) EPC had the same meaning as in the UPOV Convention and the excluding provision should only apply if such varieties were claimed *per se*. Inventions in the field of genetic engineering of plants had to be

considered technical subject-matter. The essence of the invention concerning a transgenic plant was the preparation of the DNA construct which was microbiological in nature. To discriminate against inventors investing their time, effort and resources in the production of improved plants would deprive them of the justified return on their investment.

Regarding question 3, it was submitted that Article 64(2) EPC was related to infringement proceedings to be dealt with by national law and that the provision was no basis for restricting subject-matter eligible for patent protection.

In some statements, the view was taken that methods of genetic engineering had to be considered microbiological processes within the meaning of Article 53(b), second half-sentence, EPC. Plant varieties produced by such processes should not fall within the exclusion of the first half-sentence of that Article since the provision was not restricted to the products directly obtained by a microbiological process. The opposite view was based on the argument that a microbiological process meant a process involving or performed upon or resulting in microbiological material. According to these criteria, a microbiological process could not result in a plant variety. Special treatment of genetically-produced plant varieties was not justified.

IX. The following statements objecting to the patentability of claims comprising transgenic plants were filed:

The Community Plant Variety Office (CPVO) preferred the approach according to which a claim covering, or potentially covering, a plant variety should be rejected whether or not the variety was the product of a microbiological process. The exclusion of plant varieties from patentability would be seriously undermined if it could be circumvented simply by formulating claims sufficiently widely to avoid express reference to an individual plant variety. On the other hand, the CPVO stated that they had no difficulty with the acceptance of claims in relation to plant material not in the fixed form of a plant variety which would admit the possibility of protecting a plant variety containing a patented invention. There was a conflict between

Articles 53(b) and 64(2) EPC and it should not be possible to circumvent the former by relying on Article 64(2) EPC if the product of a claimed process was a plant variety. There was no choice but to take Article 64(2) EPC into account when considering whether a claim was "in respect of" a plant variety. If this was the case the claim should be rejected.

X. Greenpeace submitted that it was not admissible to circumvent the exclusion in Article 53(b) EPC by disguising claims to plant varieties by use of broader terms such as plants, species or seed. A narrow interpretation of the provision, allowing claims to plant varieties, would be contrary to both its wording and its purpose. Nor was it possible to consider plants, plant varieties or seed as the product of a microbiological process. Furthermore, the patenting of plant varieties was contrary to the position taken by several Contracting States, in particular Germany. In addition, the patenting of seed would have negative social and economic consequences; it would especially disadvantage farmers and traditional plant breeders. Such consequences had to be considered in the framework of Article 53(a) EPC.

XI. Individuals and groups committed to the protection of the environment or animals and similar goals filed over 600 letters. The letters expressed in general terms, and to a large extent in identical wording, the concern of their authors about the grant of patents for animals and plants. They supported the approach taken in T 356/93 and T 1054/96, arguing that the patenting of plants and animals would be contrary to the wording of Article 53(b) EPC and, therefore, *contra legem*.

Reasons for the decision

1. The referral of the points of law is admissible under Article 112(1)(a) EPC.
2. Question 1 is very broad. It overlaps with questions 2 to 4 and covers numerous aspects of the examination of inventions in the field of higher life forms. It seems preferable, therefore, first to deal with the more specific questions 2 to 4. The answers to those questions will demonstrate that a separate answer to question 1 is

not required. As concerns the interpretation of the term "essentially biological processes", see point 6 below. Although the referral is considered admissible, it does not follow that all the questions posed need to be answered in the same degree of detail.

3. Question 2

Claims comprising but not individually claiming plant varieties and Article 53(b), first half-sentence, EPC

3.1 In considering whether the condition in Article 53(b), first half-sentence, EPC that "the patent is in respect of plant varieties" is fulfilled, the referring Board makes a distinction between a substantive and a literal approach. According to the substantive approach as proposed in the referring decision, a patent is said to be granted in respect of plant varieties if a claim covers plant varieties (Reasons, point 16). According to the alternative literal approach, Article 53(b) EPC is satisfied if the words "plant variety" do not appear in a claim.

Clearly, it is not the wording but the substance of a claim which is decisive in assessing the subject-matter to which the claim is directed. However, it does not follow that the subject-matter of a claim may be equated with the scope of a claim. In assessing the subject-matter of a claim, the underlying invention has to be identified. In this respect, it is relevant how generic or specific the claimed invention is. An inventor who has invented fastening means characterised in that they consist of a specific material has invented neither a nail, nor a screw, nor a bolt. Rather his invention is directed to fastening means generally. This is not a question of form but of substance: the applicant may claim his invention in the broadest possible form, ie the most general form for which all patentability requirements are fulfilled. If he has made an invention of general applicability, a generic claim is not the consequence of the verbal skill of the attorney, as the referring decision seems to suggest (Reasons, point 20), but of the breadth of application of the invention.

In the referring decision, it is expressly stated that the invention can be carried out by modifying plants which may or may not be varieties (Reasons, points 12, 13). Furthermore, it is assumed that one of the main applications of the claimed subject-matter is plant varieties (Reasons, point 11). The referring decision does not give any indication that carrying out the invention is restricted to individual varieties to be modified. Nor does the decision suggest that the result of the modification by genetic transformation is necessarily a plant variety.

Varieties have been generally considered to be the result of the breeding process (cf *Böringer*, Industrial Property Rights and Biotechnology, Plant Variety Protection No. 55, June 1988, page 45, point 1.1). In essence, this means they are the result of the processes of selection and crossing, including modern techniques such as cell fusion which do not occur under natural conditions. This seemed self-evident so long as breeding was the only way to obtain new plants. The case law of the EPO has found, drawing on Article 2(2) of the UPOV Convention 1961, that plant varieties means 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" (T 49/83, Propagating material/CIBA-GEIGY, OJ EPO 1984, 112, Reasons, point 2, confirmed in T 320/87, Hybrid plants/LUBRIZOL, OJ EPO 1990, 71, Reasons, point 13). Under Article 1(vi) of the UPOV Convention 1991, plant varieties are defined as follows:

"Variety means a plant grouping within a single botanical taxon of the lowest rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,

- distinguished from any other plant grouping by the expression of at least one of the said characteristics and

- considered as a unit with regard to its suitability for being propagated unchanged;"

The definitions in Article 5(2) of the EC Regulation on Community Plant Variety Rights as well as under Rule 23b(4) EPC, which entered into force on 1 September 1999, are identical in substance. The reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of genetic information. (*Van der Kooij*, Introduction to the EC Regulation on Plant Variety Protection, London 1997, Article 5, paragraph 2; see also *Byrne*, Commentary on the Substantive Law of the UPOV 1991 Convention, London 1991, page 20 ff).

In contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed (*Wuesthoff-Leßmann-Würtenberger*, Handbuch zum deutschen und europäischen Sortenschutz, Weinheim 1999, paragraph 116). It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part. As described in more detail in the referring decision, the claimed transgenic plants in the application in suit are defined by certain characteristics allowing the plants to inhibit the growth of plant pathogens (Reasons, point 11, Annex I, point 8). The taxonomic category within the traditional classification of the plant kingdom to which the claimed plants belong is not specified, let alone the further characteristics necessary to assess the homogeneity and stability of varieties within a given species. Hence, it would appear that the claimed invention neither expressly nor implicitly defines a single variety, whether according to the definition of "plant variety" in Article 1(vi) of the UPOV Convention 1991, or according to any of the other definitions of "plant variety" mentioned above. This also means that it does not define a multiplicity of varieties which necessarily consists of several individual varieties. In the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention is neither limited nor even directed to a variety or varieties.

3.2 However, this does not answer the question whether or not the exclusion in Article 53(b), first half-sentence, EPC applies: the provision "European patents shall not be granted in respect of plant varieties" has to be interpreted. According to the referring Board, it would be illogical to hold that those words mean that a patent should not be granted for a single plant variety but might be granted if its claims were to cover more than one variety (Reasons, point 36).

3.3 The referring Board saw no alternative, when examining a claim for the purpose of Article 53(b) EPC, to construing the claim in the same way as when considering novelty and inventive step (Reasons, point 15). For the sake of clarity, it should be noted that the approach taken by the referring Board is not an "infringement test", contrary to the appellant's submissions. In order to exclude from patenting subject-matter which is not novel or inventive, all embodiments within the claims must be examined. In contrast, the question of infringement arises when a specific embodiment is alleged to be within the scope of the claimed invention. In this case, the features of the allegedly-infringing embodiment have to be compared with the features of the relevant claim according to the rules of interpretation applied by the Courts responsible for deciding on infringement cases. This may include examining whether a feature of the claim is realised in equivalent form.

3.3.1 The referring Board came to its conclusion without refuting an argument based on the wording of the provision: whereas the exclusion for processes is related to the production of plants, the exclusion for products is related to plant varieties. The use of the more specific term "variety" within the same half-sentence of the provision relating to products is supposed to have some meaning. If it was the intention to exclude plants as a group embracing in general varieties as products, the provision would use the more general term plants as used for the processes.

3.3.2 In addition, the referring decision touches on the question whether its approach would apply not only to claims for plants embracing plant varieties but also to claims for genes contained in plant varieties (Reasons, point 22). Indeed, it can be seen as the logical consequence of the referring Board's viewpoint that any

genetic material for introduction into a plant would have to be excluded from product protection.

3.3.3 Furthermore, the approach taken by the referring Board cannot be applied consistently to all requirements for patentability. It may be helpful to look at the neighbouring exclusion in Article 53(a) EPC and ask what the situation would be if a claim were to cover something immoral or contrary to "ordre public". Suppose that a claimed invention defined a copying machine with features resulting in an improved precision of reproduction and suppose further that an embodiment of this apparatus could comprise further features (not claimed but apparent to the skilled person) the only purpose of which would be that it should also allow reproduction of security strips in banknotes strikingly similar to those in genuine banknotes. In such a case, the claimed apparatus would cover an embodiment for producing counterfeit money which could be considered to fall under Article 53(a) EPC. There is, however, no reason to consider the copying machine as claimed to be excluded since its improved properties could be used for many acceptable purposes.

A similar situation concerning the requirement of sufficient disclosure in Article 83 EPC may be found in the case law concerning biotechnological inventions. In decision T 361/87 of 15 June 1988 (not published in OJ EPO), it was decided that the non-availability of some particularly effective strains in a class of micro-organisms is immaterial so long as other suitable strains are available to the skilled person. This meant that a claim directed to the use of the whole class of micro-organisms could be granted, although specific strains comprised in this class were not available to the public. In other words, although specific embodiments covered by the claim could not be carried out, the claim was held allowable (see also T 292/85, OJ EPO 1989, 275, Polypeptide expression/GENENTECH I). Hence, the anomaly assumed by the referring Board does not exist. Rather, the examples show that the rule assumed by the referring Board that an invention is not patentable because it covers an embodiment which does not fulfil the requirements for patentability is not without exception. Therefore, the answer to the question "which interpretation is the correct one?" has to be given in the light of the context as well

as the object and purpose of the provision. It may also be observed that, in the parallel situation of animals in T 19/90 (OJ EPO 1990, 476, Onco-mouse/HARVARD, Reasons, point 4.8), the refusal of the application on the ground that the patenting of animals was excluded under Article 53(b) EPC was set aside and the case was referred back to the Examining Division to examine whether the subject-matter of the application was an animal variety.

3.4 The referring decision states correctly that Article 53(b) EPC is derived from Article 2(b) of the Strasbourg Patent Convention (SPC). The historical background may contribute to an understanding of Article 53(b) EPC since the provisions on patentability thereof follow closely the corresponding provisions in the SPC (*Haertel*, Münchner Gemeinschaftskommentar zum EPÜ, Einführung, München 1984, Geschichtliche Entwicklung, paragraph 28; *Mousseron*, Traité des Brevets, Paris 1984, paragraph 145, at page 165). The provision on plant varieties in the SPC, however, differs in an important respect from its counterpart in the EPC: whereas in Article 53(b) EPC plant varieties are excluded, Article 2(b) SPC stipulates that "the Contracting States **shall not be bound to provide for the grant of patents** in respect of plant varieties" (emphasis added). In other words, the EPC opted for a particular approach, whereas the SPC left the matter open to national legislators as one of several possibilities.

This open-ended approach in the SPC was provided in order to solve a dilemma for the legislator which would otherwise have existed: on the one hand, SPC Contracting States are obliged under Article 1 SPC to grant patents for any inventions which are susceptible of industrial application, which are new and involve an inventive step. On the other hand, UPOV member States were allowed under Article 2(1) UPOV Convention 1961 to recognise the right of the breeder by the grant of either a special plant breeders' right or of a patent; however, simultaneous protection for the same botanical genus or species was not allowed. This so-called ban on dual protection (abandoned in the UPOV Convention 1991) made it necessary for member States of the Council of Europe to exclude patent protection for varieties for which plant breeders' rights were obtainable (*Mousseron*, supra, paragraph 429, at page 449;

Germany: Denkschrift zum Straßburger Patentübereinkommen, Bundestagsdrucksache 73712, zu Artikel 2, page 379, first paragraph). Thus, under the SPC, plant varieties were not regarded per se ineligible for patent protection. Rather, this question was left open intentionally (Denkschrift, supra, page 378, last full paragraph).

It was clear at the time that processes for the production of higher life forms and the products thereof involved special problems concerning the criteria for patentability, in particular, as regards reproducibility. However, in different European countries, patents were granted for varieties (for Germany see *Wuesthoff*, *Biologische Erfindungen im Wandel der Rechtsprechung*, GRUR 1977, 404, at page 407; for other countries see *Neumeier*, *Sortenschutz und/oder Patentschutz für Pflanzenzüchtungen*, Köln 1990, page 31 ff). In implementing Article 2(b) SPC, several Contracting States excluded the grant of patents only for varieties included in the list of varieties annexed to the Plant Varieties Protection Law (Belgium: Article 4(1) n° 1 de la loi du 28 mars 1984; Germany: § 1(2) Nr. 2 PatG 1968 idF des Sortenschutzgesetzes v. 20. Mai 1968; France: Art. 7(2), paragraphe 4, de la loi n° 68-1, comme modifiée par l'Art. 34 de la loi n° 70-489; Spain: Art. 5(1)(b) of the Law 11/1986 on Patents. See also Groups Reports on Question 93 - Biotechnology, AIPPI Annuaire 1987/V). The UPOV Convention 1961 did not oblige its member States to protect varieties belonging to all botanical genera and species but provided in its Article 4 for the progressive application of its provisions. Therefore, in the early years of UPOV, plant breeders' rights were only available in respect of a few species in the above countries, whereas in respect of the majority of species patentability was not excluded. In summary, it is clear from Article 2(b) SPC and its implementation by some of its Contracting States that this provision was not based on the concept that there should be no patent protection for plant varieties. Rather, it was intended to ensure that Contracting States should not be bound to grant patents for subject-matter for which patents were excluded under the ban on dual protection in the UPOV Convention 1961. This leaves open the question whether the purpose of Article 53(b) EPC differs from the corresponding SPC provision.

3.5 When the legislator drafted the requirements for patentability in the EPC, the basis was the harmonisation already achieved by the SPC in the framework of the Council of Europe (Memorandum on the setting up of a European system for the grant of patents, Doc. BR/2/69, section II.1; Reports on the Preliminary Draft Convention for a European System for the Grant of Patents, Luxembourg 1970, General Report, point 5; Article 10(b) of this Draft is identical with the final version of Article 53(b) EPC). In the early nineteen sixties, the work on both Conventions proceeded in parallel. Whereas it was possible for most provisions of the SPC concerning patentability simply to be transferred to the EPC, this was not the case with Article 2(b) SPC since a choice had to be made whether or not to make use of the possible exclusion of patents in respect of plant varieties. It was not appropriate for the legislator to allow the grant of patents for plant varieties in general because some EPC Contracting States offered plant variety protection under the UPOV system and were prevented under the ban on dual protection from granting patents. Nor was it possible under the EPC to exclude patent protection only in respect of those varieties for which a plant breeders' right was available (the approach taken by Belgium, Germany, France and Spain in their national legislation, see the preceding point). Plant breeders' rights at a European level were not available and at the national level the availability of plant breeders' rights differed from country to country. To take account of the specific situation in each designated State for each individual application would have been contrary to the principle of uniform patent protection in all Contracting States (cf Article 118 EPC). For these reasons, the most obvious choice was to make full use of the possibility in Article 2(b) SPC to exclude the grant of patents in respect of plant varieties entirely (*Mousseron, supra*, paragraph 429, at page 450).

3.6 This background suggests that the purpose of Article 53(b) EPC corresponds to the purpose of Article 2(b) SPC: European patents should not be granted for subject-matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention 1961. This is confirmed by the brief remark in the travaux préparatoires to the effect that the provision in the EPC simply follows

Article 2 of the Strasbourg Convention (Reports on the Preliminary Draft Convention, *supra*, Report by the British Delegation on Articles 1 to 30, page 12, point 25).

3.7 Accordingly, inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC provided they fulfilled the other requirements of patentability.

The idea that the exclusion in the EPC should correspond to the availability of protection in UPOV was expressed in the early stages of the preparatory work on the EPC. In the remarks on Article 12 of the *Haertel* Draft 1961 proposing the exclusion of inventions relating to processes of breeding of plant or animal varieties, it was said that it remained to be considered whether the patentability of technical processes for breeding new plants (eg by radiation) had to be taken expressly into the Draft or whether this was self-evident from general principles. Previously, in the "*Haertel* Study" of 7 July 1960 (page 13f), the parallel work on the preparation of the UPOV Convention was mentioned in connection with possible exceptions to patentability.

This corresponds to remarks made by *Pfanner* on Article 2(b) SPC after the majority of member States of the Council of Europe had decided to protect plant varieties by plant breeders' rights and not by patents (*Vereinheitlichung des materiellen Patentrechts im Rahmen des Europarats*, GRUR Int. 1962, 545, at page 548). Moreover, in the EEC "Patents" Working Party the distinction between biological and technical breeding processes was also discussed (Report on the 5th meeting, Doc. IV/2767/61, page 8). After consultation with interested parties, it was decided to add a clarification to Article 10b of the May 1962 Draft according to which the exclusion did not apply to microbiological processes and the products thereof (Report on the 10th meeting, Doc. 9081/IV/63, page 65). This historical background shows at least an intention to protect by the plant breeders' rights system biological developments for which the patent system was less suited (*Pfanner*, *supra*) and to keep technical inventions related to plants within the patent system.

There is nothing in the travaux préparatoires to suggest that Article 53(b) EPC could or even should exclude subject-matter for which no protection under a plant breeders rights' system was available. From the plant breeders' side, representations were also made calling for the elements of plant variety protection and patent protection to be harmonised in such a way that together the two forms of protection would constitute a single comprehensive system of industrial property protection for plant innovations permitting neither overlapping nor gaps in the protection of eligible subject-matter (*Böringer*, supra, at point 3.2.3). In this respect, the purpose of Article 53(b) EPC is quite different from the purpose of Article 52(4) EPC. In the latter provision, gaps in the protection of eligible subject-matter are deliberately accepted in order to free from restraint non-commercial and non-industrial medical and veterinary activities (G 5/83, OJ EPO 1985, 64 - Second medical indication/EISAI, Reasons, point 22). Therefore, the comparison drawn in the referring decision with Article 52(4) EPC (Reasons, points 62 ff) does not assist in arriving at the correct interpretation of Article 53(b) EPC.

3.8 It has already been stated that the subject-matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties (see above point 3.1). It follows that such an invention cannot be protected by a plant breeders' right which is concerned with plant groupings defined by their whole genome but not by individual characteristics (*Greengrass*, Recent Phenomena in the Protection of Industrial Property, Plant Variety Protection No. 57, 1989, page 28, at page 57). Whereas in the case of a plant variety, the breeder has to develop a plant grouping fulfilling in particular the requirements of homogeneity and stability, this is not the case with a typical genetic engineering invention in a claim such as that referred to in question 2. The inventor in the latter case aims at providing tools whereby a desired property can be bestowed on plants by inserting a gene into the genome of those plants. Providing these tools is a step which precedes the further step of introducing the gene into a specific plant. Nevertheless, it is the contribution of the inventor in the genetic field which makes it possible to take the second step and insert the gene into the genome of any appropriate plant or plant variety. Choosing a suitable plant for this purpose and arriving at a specific, marketable product, which will mostly be a

plant variety, is a matter of routine breeding steps which may be rewarded by a plant breeders' right. The inventor in the genetic engineering field would not obtain appropriate protection if he were restricted to specific varieties for two reasons: first, the development of specific varieties will often not be in his field of activity and, second, he would always be limited to a few varieties even though he had provided the means for inserting the gene into all appropriate plants.

3.9 The objections to patentability submitted by Greenpeace under Article 53(a) EPC fall outside the scope of the referred questions. The Board recognises that these objections raise questions which are of interest to many members of the public. It is, therefore, appropriate to note that Article 52(1) EPC expresses the general principle of patentability for inventions which are industrially applicable, new and inventive (G 5/83, supra, Reasons, point 22). The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and of restricting the field of patentable subject-matter accordingly. The standard to apply for an exclusion under Article 53(a) EPC is whether the publication or the exploitation of the invention is contrary to ordre public or morality. Although the positions adopted in society on genetic engineering are controversial (see eg the contributions in Eposcript Vol. 1, Munich 1993, Genetic Engineering - The New Challenge), there is no consensus in the Contracting States condemning genetic engineering in the development of plants under the above criteria. On the contrary, the Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions (No. 98/44/EC of 6 July 1998 [hereinafter: Biotechnology Directive]) establishes that promotion of innovation in this field is considered necessary in Europe. In particular, Article 12 thereof takes account of the interests of the breeder who cannot acquire or exploit a plant variety right without infringing a patent. Under the conditions of paragraph 3 of the provision, the breeder is entitled to a compulsory licence subject to payment of an appropriate royalty. The possibilities of the patentee to use the patent as a means of restricting access to important breeding material are thereby substantially restricted.

3.10 In summary, according to Article 53(b) EPC, a patent is "in respect of plant varieties" and shall not be granted if the claimed subject-matter is directed to plant varieties. In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within the meaning of Article 53(b) EPC. This is why it is, contrary to the conclusions of the referring Board, in agreement with the rules of logic that a patent shall not be granted for a single plant variety but can be granted if varieties may fall within the scope of its claims. The conclusion of the referring Board is based on the premise that a claim is necessarily "in respect of" a certain subject if it may comprise this subject. For Article 53(b) EPC, this interpretation is, as set out above, at odds with the purpose of the provision. It disregards the fact that Article 53(b) EPC defines the borderline between patent protection and plant variety protection. The extent of the exclusion for patents is the obverse of the availability of plant variety rights. The latter are only granted for specific plant varieties and not for technical teachings which can be implemented in an indefinite number of plant varieties. This is not a question of arithmetical logic but based on the purpose of plant variety rights to protect specific products which are used in farming and gardening (*Wuesthoff-Leßmann-Würtenberger*, supra, paragraph 96). Similarly, the example given in amicus curiae briefs stating that polygamy cannot be allowed if bigamy is forbidden, although plausible at first glance, turns out to be less persuasive. In the same way as the ban on bigamy forbids marrying several persons, it is not permitted to claim several specific plant varieties. It is not sufficient for the exclusion of Article 53(b) EPC to apply that one or more plant varieties are embraced or may be embraced by the claims.

4. Question 3

The relevance of Article 64(2) EPC

Although put more broadly, the question seems to relate to process claims only (see Reasons, points 80, 88). Taking as its starting point that plant varieties must not be covered by claims to plants, the referring Board poses the question whether under

Article 64(2) EPC process claims can be allowed when the product directly obtained by the claimed process is or covers a plant variety. In the light of the answer to the preceding question, question 3 appears to have lost its relevance: if a plant variety may be covered by a product claim, there is little room for the argument that protection for the variety derived from a claimed process could be inconsistent therewith. For the avoidance of any doubt, **question 3** is answered in conformity with the established case law according to which the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable per se (Case Law of the Boards of Appeal of the EPO, 3d ed. 1998, II.B.6.1 and 6.2). This practice takes account of the purpose of the provision and is in accordance with its location in the EPC. The requirements on patentability to be examined by the EPO are contained in Part II, Chapter I EPC (Articles 52 to 57); Article 64(2) EPC belongs to Part II, Chapter III, containing provisions concerning the effects of patents and patent applications and is to be applied by the Courts responsible for deciding on infringement cases. The referring Board also comes to the conclusion that Article 64(2) EPC does not affect the examination of claims for the manufacture of plants (Reasons, point 88). The protection of the product obtained by a patented process is of particular importance in situations where product protection is not available (*Hahn*, Der Schutz von Erzeugnissen patentierter Verfahren, Köln 1968, page 196 ff; *Mathély*, Le droit européen des brevets d'invention, Paris 1978, page 368 ff). From this purpose it also becomes clear that the protection of the product obtained by a patented process has nothing to do with product-by-process claims which, although containing process features, belong to the category of product claims, whereas the derived product protection is the effect of a process claim (BGH 1 IIC 136 - Red Dove, Reasons, II.B.2).

5. Question 4

Plant varieties as products of processes using recombinant gene technology

5.1 In answering question 4 one could consider the genetic modification of plant material to be a microbiological process within the meaning of Article 53(b), second half-sentence, EPC. Starting from the assumption that Article 53(b), second half-sentence, EPC is *lex specialis*, it could be concluded that the *lex generalis* in the first half-sentence of the provision does not apply to situations covered by the *lex specialis*.

5.2 Processes of genetic engineering, however, are not identical with microbiological processes. The term microbiological processes in the provision was used as synonymous with processes using micro-organisms. Micro-organisms are different from the parts of living beings used for the genetic modification of plants. On the other hand, it is true that cells and parts thereof are treated like micro-organisms under the current practice of the EPO (T 356/93, Plant cells/PLANT GENETIC SYSTEMS, OJ EPO 1995, 545, Reasons, points 32 to 34). This appears justified since modern biotechnology has developed from traditional microbiology and cells are comparable to unicellular organisms.

5.3 This does not, however, mean that genetically-modified plants are to be treated as products of microbiological processes within the meaning of Article 53(b), second half-sentence EPC. Such an analogy and formal use of rules of interpretation would disregard the purpose of the exclusion as identified above (Point 3.6 ff). The exclusion in Article 53(b) EPC was made to serve the purpose of excluding from patentability subject-matter which is eligible for protection under the plant breeders' rights system.

As already emphasised by the referring Board, it does not make any difference for the requirements under the UPOV Convention or under the Regulation on Plant Variety Rights, how a variety was obtained. Whether a plant variety is the result of traditional breeding techniques, or whether genetic engineering was used to obtain a distinct plant grouping, does not matter for the criteria of distinctness, homogeneity and stability and the examination thereof. This means that the term "plant variety" is appropriate for defining the borderline between patent protection and plant breeders'

rights protection irrespective of the origin of the variety. The argument that the legislator of the EPC did not envisage the possibility of genetically- modified plant varieties and for this reason could not have had the intention of excluding them from patentability cannot be accepted. Laws are not restricted in their application to situations known to the legislator. Since plant varieties are excluded, the only question is the conditions under which they are excluded. The Enlarged Board of Appeal supports the view of the referring Board (Reasons, point 92) that the mere fact of being obtained by means of genetic engineering does not give the producers of such plant varieties a privileged position relative to breeders of plant varieties resulting from traditional breeding only. Given the purpose of Article 53(b) EPC, **question 4** has to be answered in the negative. Article 4(1)b and (3) of the Biotechnology Directive, using language corresponding to Article 53(b) EPC, is intended to be interpreted in the sense outlined above, since Recital 32 of the Directive postulates that a new plant variety bred as a result of genetically modifying a particular plant variety is still excluded from patent protection, even if the genetic modification is the result of a biotechnological process.

6. *Question 1*

Extent of examination under Article 53(b) EPC

Most of the problems discussed by the referring Board under question 1 have been dealt with in the replies to questions 2 to 4. This is not the case with the question how to decide whether a process can be defined as an "essentially biological process".

In respect of the method of preparing transgenic plants claimed in the application in suit, the referring decision raised the objection that the claims were not clear and concise because no identifiable method steps were recited (Reasons, point 23 ff). Instead, every means of obtaining the stated plant were claimed, including "essentially biological processes for producing plants" which would fall under the prohibition of Article 53(b), first half-sentence, EPC. In considering the crossing step

using conventional breeding techniques, issues arose as to what process steps were allowable in a claim having regard to that prohibition. In its observations to the Enlarged Board of Appeal on the referring decision, the appellant explained not having been made aware of the objections earlier. The appellant expressed its willingness to make the required amendments to meet these formal objections. It may be assumed from that offer that the appellant is willing to restrict the method claims to identifiable method steps in order to exclude essentially biological processes. In this situation, the relevance to the application having given rise to the referral of the question how to decide whether a process can be defined as an essentially biological process has not yet been clarified. To offer guidance in this respect without having a sound factual basis for doing so is inappropriate.

For these reasons, there is no need for any further reply to **question 1** beyond the answers already given to questions 2 to 4.

Order

For these reasons it is decided that:

The questions of law referred to the Enlarged Board of Appeal are answered as follows:

1. See answers to questions 2 to 4.
2. A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties.
3. When a claim to a process for the production of a plant variety is examined, Article 64(2) EPC is not to be taken into consideration.

4. The exception to patentability in Article 53(b), first half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.