

DECISIONS OF THE BOARDS OF APPEAL

**Referral-Decision of Technical Board of Appeal 3.3.4 dated
13 October 1997**

T 1054/96 - 3.3.4* **

(Language of the proceedings)

Composition of the board:

Chairman: U. M. Kinkeldey

Members: F. L. Davison-Brunel
S. C. Perryman

Applicant: NOVARTIS AG

Headword: Transgenic plant/NOVARTIS

Article: 33(1)(b), 52, 53(b), 54, 64(2), 84, 112(1), 164(2), 172 EPC

Keyword: "Claims encompassing plant varieties" - "Genetically engineered plant varieties" - "Essentially biological processes for the production of plants" - "Varieties as products of microbiological processes" - "Contravention of prohibition of Article 53(b) EPC" - "Referral to Enlarged Board (yes)"

Headnote

The following questions are referred to the Enlarged Board of Appeal for decision:

I. 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?

II. 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?

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

IV. 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?

Summary of facts and submissions

I. European patent application No. 91 810 144.5 published under No. 0 488 511 with the title "Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes" was refused by the Examining Division.

Claim 19 as refused read as follows:

"A transgenic plant and the seed thereof comprising recombinant DNA sequences encoding

- a) one or more lytic peptides, which is not lysozyme, in combination with;
- b) one or more chitinases; and/or
- c) one or more beta-1,3-glucanases in a synergistically effective amount."

Claims 20 to 22 were directed to further embodiments of the subject-matter of claim 19.

Claims 23 and 24 read as follows:

"23. A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides together with one or more chitinases; and/or one or more beta-1,3-glucanases in a synergistically effective amount; said method comprising the steps of preparing a transgenic plant comprising recombinant DNA sequences encoding one or more lytic peptides, which is not lysozyme together with one or more chitinases; and/or one or more beta-1,3-glucanases.

24. A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides which is not lysozyme together with one or more chitinases; and/or one or more beta-1,3-glucanases in a synergistically effective amount; said method comprising the steps of preparing two or more transgenic plants comprising recombinant DNA sequences encoding one or more lytic peptides together with one or more chitinases; and/or one or more beta-1,3-glucanases, and crossing said plants using conventional breeding techniques."

II. The Examining Division refused the application under Article 97(1) EPC for the reason that claims 19 to 22 did not fulfill the requirements of Article 53(b) EPC. A parallel was drawn with the case dealt with in decision T 356/93 (OJ EPO 1995, 545) where genetically engineered plants and seeds were equally claimed. The Examining Division remarked that, in this earlier case, the Board had held that a claim to genetically engineered plants and seeds, although not directed to any specific plant

varieties, encompassed plant varieties which were not products of a microbiological process and, consequently, was not allowable under Article 53(b) EPC.

III. The Appellant lodged an appeal against this decision requesting that the decision under appeal be set aside and a patent be granted on the basis of the set of claims before the Examining Division. In particular it was argued that decision T 356/93 (loc. cit.) had inappropriately interpreted Article 53(b) EPC and should not be followed.

IV. The Board issued a summons to oral proceedings, and sent a communication dated 5 September 1997, in which objections were also raised to claims 23 and 24, the preliminary view of the Board on issues to be discussed was set out, and in which the Appellant was asked to consider adding a disclaimer at the end of claim 19 in the form of "protection for plant varieties for which European patents shall not be granted pursuant to Article 53 EPC is disclaimed".

V. Oral proceedings took place on 13 October 1997. After discussion of various proposals by the Appellant and the Board of questions for referral to the Enlarged Board of Appeal, the Appellant submitted a document headed "Revised questions for Enlarged Board" reading:

1. What duties do the instances of the EPO have regarding examining an application in respect of whether the claims are allowable in view of the provision of Article 53(b) 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; in particular, are the instances of the EPO obliged to take into account relevant provisions of international conventions on which EPC Contracting States have agreed such as the TRIPS agreement, EU directives, the Agreement on Community Patent, the UPOV Convention, etc., in the sense of "subsequent practice" of Article 31(3) of the Vienna Convention on the Law of Treaties and the necessity to pay attention to questions of harmonization of

national and international rules of law as stated by the Enlarged Board of Appeal in G 05/83?

2. Does a claim which is based on a technical contribution the application of which is not confined to a single or particular plant variety and 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 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, apply to a claim for a plant grouping in which each individual plant of that grouping contains at least one specific gene introduced into an ancestral plant by recombinant gene technology?

VI. Insofar as relevant to understand the context of the referral the submissions of the Appellant at the oral proceedings can be summarized as follows:

In relation to claim 19

(a) Claim 19 related to a generally applicable technical contribution for making plants with desired properties because they contained a set of desired genes. Emphasis should be put on "generally applicable technical contribution". Discrimination against technical inventors that made broadly applicable technical contributions had to be avoided. Only patents were available to protect such broad general contributions to the art, and if technical inventors did not get patent protection for such inventions they were left with nothing at all. Patent protection should be available provided a

variety was not claimed as such, and this view was supported by various authors and by reference to various other treaties and to legislative proposals.

(b) The Appellant was not satisfied with process claims. It was a quite normal practice that somebody who had invented a compound should be entitled to all possible categories of claims. Why should somebody who had made a technical contribution with which he could make a multitude of transgenic plants, be limited to method claims?

(c) If an applicant had to insert a disclaimer of plant varieties when claiming plants because otherwise the claim also encompassed plant varieties, then it would also be necessary to ask for disclaimers of plant varieties in all cases where an applicant claimed a gene, because here too it could be argued that the claim to the gene encompassed also every plant variety containing that gene. There was no basis for such a requirement of a disclaimer of plant varieties in claims to genes.

On treaty interpretation

(d) The view taken in its communication by the Board on how to interpret the EPC namely that the treaty must be interpreted in good faith, that unless it was established that the Contracting States intended that a special meaning be given to a term, the term of the Treaty should be given its ordinary meaning in its context and in the light of the object and purpose of the EPC was too narrow. The basic rules of the Vienna Convention for the interpretation of treaties had to be applied as acknowledged twice by the Enlarged Board. Article 31 of the Vienna Convention: General Rules of interpretation, in particular Article 31 part 3 made clear that there was no necessity to have a formal agreement to establish a subsequent practice. It was sufficient that all parties accept that practice, and acceptance might mean a qualified silence as acquiescence. This was important in view of the fact that the Contracting States of the EPC were not all EU members, nor were all of them members of all other conventions or treaties.

(e) Article 32 of the Vienna Convention: supplementary means of interpretation stated that recourse might be had to supplementary means of interpretation to confirm the meaning resulting from the application of Article 31. This applied only if there was no clear subsequent practice. If it was possible to derive a clear interpretation from subsequent practice, there was no room for the application of Article 32.

(f) The classical view on interpreting a convention was that "It is a general principle of law, which has been applied in many contexts that a party's attitude, state of mind or intentions at a later date can be regarded as good evidence in relation to the same or closely related matter of his attitude, state of mind or intentions at an earlier date also..." Further it was established international public law that the subsequent practice need not necessarily be directly under the Treaty which had to be interpreted but could be demonstrated in other international treaties as long as there was a demonstrated link to a provision which had to be interpreted.

(g) In this case other treaties and conventions cited by the Appellants related directly to Article 53(b) EPC, and thus were subsequent practice to be taken into account.

(h) After the Vienna Convention, the International Court of Justice demonstrated that the subsequent practice could and should be used as an independent **primary** means of interpretation and that the dynamic interpretation of conventions according to the International Court of Justice amounts to considering that the purpose and the goal of a Treaty are not petrified by the will of the parties when they concluded the treaty. Taking into account the subsequent practice does not disconnect the intentions, attitudes and minds of the parties, to the contrary it follows their minds. By no means can subsequent practice modify a convention. It has to be regarded only as a means to clarify and complement the terms used in the treaty.

(i) In connection with the Community Patent Convention 1975 there was discussed a parallel provision to Article 64 EPC, the original wording of which parallel provision

was that the direct products of a process were to be covered by the process patent. There was a proposed addition "insofar as such product is not a plant or animal variety excluded from patent protection under Article 53 of the European patent convention". France and Great Britain refused the suggested amendment "in order to take into account Articles 64 and 53(b) (second part) of the EPC itself which provide that plant and animal varieties may not be protected **as such**".

(j) In the same manner in the Strasbourg Convention, all they had in mind when they wrote the exception to the exception, were microbes and antibiotics. To deduce therefrom what they had in mind for the processes for the production of animal and plants is not tenable.

(k) Where an invention in plants can be used in more than one plant variety, according to the will of the EU states, there should be a patent and when interpreting the EPC, account should be taken of the definition of variety adopted in the UPOV convention.

(l) All EU Contracting States but Monaco are bound by the TRIPS agreement. Fifteen Contracting States are bound by the EC regulations on community plant variety rights clearly interpreting the exclusion in Article 53(b) EPC as being limited to plant varieties as such. Switzerland already has Guidelines in line with the EC directives, as does Liechtenstein. Monaco has no provisions, but here silence can in line with the usual international rules on interpretation be treated as acquiescence.

(m) The draft EC directive has not yet come into force, but even if it should fail to enter into force, it would still be evidence how member states interpret and understand the requirements of Article 53(b) EPC.

(n) The EPC was a harmonising convention. When a question of interpretation arose there was an obligation on the Board to look at where the national laws were going and whether a common thread was running through them. If there was, that had to

be taken into account. There was an obligation to look forward to see where the Contracting States were going.

(o) **Embodiments within the claim would include plant varieties. That was accepted.** The misunderstanding by the Board was to use an approach that was only sound when approaching the question of novelty. For novelty it was appropriate to ask whether there was an embodiment covered by the claim, which embodiment was not novel. In that case the claim would be bad for lack of novelty. But that approach was a completely inappropriate approach in relation to plant varieties. The rule under Article 53(b) EPC was a rule about the form that the claim took, not about what it covered. You could claim in a form which was a higher taxonomic group than a variety, and the fact that the claim contained varieties was alright. If, however, you formulated your claim as a claim to a variety, then that was bad.

(p) There was a clear distinction between the subject-matter eligible for patent protection and the subject-matter eligible for the plant variety protection. It was not certain that plant varieties as understood under the plant varieties protection laws were encompassed by the claim because there was always additional work needed to get the plant variety. What was at stake here was a technical teaching. The appellant represented a branch of industry at the same time producing a technical teaching and plant varieties. So if they will produce a new plant variety out of this, then it will be commercially used and then, as plant varieties in the commerce, the farmer will get the same treatment as with any other plant varieties.

(q) Article 52(4) EPC had a quite different logic behind it, namely that patents should not interfere with the activities of doctors and veterinary surgeons. Therefore applicants generally accepted disclaimers of therapeutic or surgical uses. This was based on ethical reasons.

(r) In contrast, the logic behind Article 53(b) was that for plant varieties, account had to be taken that these could also be protected by a different form of rights. But the

technique for producing offspring with better traits should be protectable also under patent law, as the technique could not be generally protected under plant variety rights.

(s) Article 52(2)(3) EPC is concerned with whether something which contained a discovery, computer program, etc. could be protected. The limitation "as such" in Article 52(3) EPC ensures that if there is matter in addition to the discovery, computer program etc. then patentability is not excluded.

(t) In Article 53(b) EPC the delimitation is given by the definition of plant varieties as defined in the UPOV convention.

(u) Claim 19 also covered other plants than plant varieties.

(v) In the text of Article 53(b) EPC plants and animals are considered together, but in applying the rules of interpretation to this the Boards may need to take account of the fact that the original situation for plants and the way the practice of the Contracting States has developed is quite different than for animals.

VII. At the end of the oral proceedings the Appellant requested that the questions on points of law in the document headed "Revised questions for Enlarged Board" submitted at the oral proceedings on 13 October 1997 be referred to the Enlarged Board of Appeal, and that on receipt of the answer the appellant be given an opportunity to make further requests and submissions.

Reasons for the Decision

1. The four questions referred by the Board to the Enlarged Board of Appeal (EBA) can be found together at the end of this decision. Each single question is furthermore set out before being discussed in detail.

2. The Board has not referred all the questions proposed by the appellant (see point V, above). Specifically the part of question 1 put forward by the Appellant reading:

"...in particular, are the instances of the EPO obliged to take into account relevant provisions of international conventions on which EPC contracting states have agreed such as the TRIPS agreement, EU directives, the Agreement on Community Patent, the UPOV Convention, etc., in the sense of "subsequent practice" of Article 31(3) of the Vienna Convention on the Law of Treaties and the necessity to pay attention to questions of harmonization of national and international rules of law as stated by the Enlarged Board of Appeal in G 05/83"

was considered by the Board too vague.

3. The Board would agree that, in theory, clearly established "subsequent practice" should be taken into account, but in this case it has difficulty in identifying anything as a clearly established subsequent practice by the Contracting States to the European Patent Convention (see points 66 to 77 below). Even if there were an established practice, the Board has doubts whether it would be practicable or desirable for arguments relating to a "subsequent practice" to be gone into on each patent application by every instance of the EPO. A preferable course would seem to be for the subsequent practice either to be acknowledged by the Guidelines for Examination, which, pursuant to Article 23(3) EPC, are not binding on the Boards of Appeal, and thus open to challenge before the latter in appeal proceedings, or for the subsequent practice to be argued for and possibly successfully established in the course of appeal proceedings before the Boards, or a referral to the Enlarged Board of Appeal such as the present.

4. Question 2 as suggested by the Appellant was considered not to identify clearly enough the type of claim concerned when speaking of "a claim which is based on a technical contribution the application of which is not confined to a single or particular

plant variety". For the Board the most natural meaning of this is a reference to a process claim, but the Appellant seems to be considering this in relation to a claim to a plant. The relevant considerations and the legal result arrived at are likely to be different dependent on whether the claim under consideration is for a process or for a plant.

5. Question 4 as suggested by the Appellant is considered objectionable in that it refers to "a claim for a plant grouping in which each individual plant of that grouping contains at least one specific gene introduced into an ancestral plant by recombinant gene technology". The term "plant grouping" does not occur in the EPC; it occurs in UPOV 1991 when defining plant variety as "a plant grouping within a single botanical taxon of the lowest known rank". Thus in UPOV 1991 the term "plant grouping" relates to extremely closely related plants (see Annex V). The concept of "a plant grouping which is characterized by a particular gene (and not its whole genome)" now appears in recital (31) of the proposed EU directive but nowhere else in the directive (see point 95 below). This use of "plant grouping" in the proposed EU directive has no relation to the use of "plant grouping" in UPOV 1991. To put a question to the Enlarged Board of Appeal using the term "plant grouping" would merely serve to obscure already difficult subject-matter.

6. The claims in the patent application giving rise to the present referral raise questions both as to what types of product claim and as to what types of method claim are to be considered incompatible with the prohibition of Article 53(b) EPC. This Board is seeking answers at the level of whether a particular type of claim is compatible with Article 53(b) EPC or not.

Technical Background to referral

7. In case it is of assistance to the Enlarged Board of Appeal, a brief explanation of the technical background, and a glossary of technical terms are provided in Annexes I and II to this decision. Annex III provides excerpts of the preparatory

material for the European Patent Convention whereas Annex IV provides excerpts of the Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights. The definitions of the term "plant varieties" following UPOV 1961 and UPOV 1991 are given in Annex V.

First question to the Enlarged Board of Appeal

8. The question reads:

"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?"

*To what extent should the instances of the EPO examine an application in respect of whether **product claims to plants** are allowable in view of the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties?*

9. The Appellant argued that the substantive approach to examination in use at the European Patent Office, as, for example, with regard to assessing novelty, was not suited to determine whether a claim encompassed subject-matter for which patents shall not be granted according to Article 53(b) EPC. In his opinion, a formal approach would be the correct one.

The substantive approach

10. The question of what a European patent is granted in respect of, has to be answered by referring to the claims, which in accordance with Articles 69 (including its protocol) and 84 EPC define the matter for which protection is sought and should

be read in the context of the description. In the Board's view, it is thus necessary to decide, irrespective of the precise wording used, whether any claim is in whole or in part directed to subject-matter for which a patent shall not be granted under Article 53(b) EPC.

11. The application relates to the control of plant pathogens in agricultural crops and claims not only a process for preparing transgenic plants, but also the transgenic plants according to claim 19. Traditionally and in modern technological agriculture as well, the aim of the breeder is likely to be the production of plants of a particular variety, so that the crops mature uniformly and stably to a desired phenotype, e.g. in the present case with a characteristic being resistance against a plant pathogen. National regulations may provide that only seeds of recognized plant varieties may be offered for sale. As a practical matter it must thus be assumed that one of the main applications of the here examined subject matter is plant varieties. The fact that plant varieties are thus covered by the claims cannot be ignored.

12. The Appellant in fact accepted (see point VI(o) above) that embodiments within the claim would include varieties. Furthermore, the Board observes that the present application is not the only example where the specification gives technical information emphasizing that a stable insertion of a desired gene into an existing plant variety leads to material which differs from the transformed starting material only in the desired feature. For example, the patent which is the subject of decision T 356/93 (loc. cit.) and European patent application 0 429 093 column 16, lines 5 to 11 also disclose that the modification by recombinant DNA technique of a starting plant variety is stable and does not lead to undesired changes of the genotype of the plant.

13. The Appellant argued that claim 19 also covered plants which would not belong to a plant variety. The Board agrees that this is so.

14. If it is correct to look at the substance of the claim, it would thus be the Board's conclusion that claim 19 directed to a genetically modified plant covers two types of embodiments, one of them being plant varieties i.e. that claim 19 is a claim *inter alia* for plant varieties.

15. For examination of a claim for the purpose of Article 53(b) EPC, the Board sees no alternative to construing the claim in the same way as is done for considering novelty or inventive step.

16. The normal principle adopted on interpreting patent claims for these latter purposes is that a patent is granted for everything falling within the scope of the claim. If a claim to a plant also covers varieties, then a patent is being granted in respect of those varieties.

The literal approach

17. Another approach to examination is the literal approach. On this, all that is required of the patent office is to check that the words "plant variety" (or the equivalent French and German terms) do not appear in any claims. If these words do not appear, then Article 53(b) EPC is satisfied in relation to a claim to a plant. This would make examination for conformity with Article 53(b) EPC a very facile procedure.

18. The Board has difficulty in believing that the drafters of the EPC (and those of the Strasbourg Convention) would have included the provision of Article 53(b) EPC merely to prevent these words appearing in a claim, but without intending the provision to have any substantive function. The purpose suggested for this provision by the Appellant was to achieve harmonisation with UPOV 1961. However, this answer firstly leaves open the question of what purpose the provision in Article 53(b) EPC excluding animal varieties from the grant of a patent was to achieve. There was no provision for industrial property rights specifically for animal varieties. And

secondly, the answer would ignore that also in UPOV the term "plant variety" has a technical content.

Conclusion

19. The Board's conclusion is that the substantive approach is the correct one to be applied when examining claim 19 for allowability in the light of Article 53(b) EPC. Thus, every potential embodiment of the subject-matter of claim 19 is either a plant variety or not. Insofar as it is a plant variety, it is not patentable. Insofar as it is not a plant variety, it is patentable. Higher taxonomic categories such as species, genus, family or order may be relevant as a convenient description of the field of application amongst existing plants of an invention, but for a particular embodiment the only relevant question is whether it is a plant variety or not. An embodiment cannot by itself be a species, genus, family or order.

20. For the EPO to adopt the literal approach would, in effect, be to abdicate any responsibility for examining the substance of the claim, and the outcome of an application would depend on the verbal skill of the patent attorney concerned.

21. In an attempt to accommodate the request for the patenting of plants modified by gene technology while respecting the prohibition under Article 53(b) EPC, the Boards of Appeal in case T 356/93 (*loc. cit.*) and in the present case suggested the introduction into the claims of a disclaimer to plant varieties. This suggestion was not taken up in either case.

22. The present Appellant has also argued that if a disclaimer of plant varieties was necessary in a claim relating to plants, then it would also be necessary to disclaim "genes contained in plant varieties" in a claim relating to a gene (see point VI(c) above). This is not a matter relevant to any claims in the present application, or to the questions referred, so that the Board considers that no comment is required.

*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) that patents shall not be granted in respect of **essentially biological processes** for the production of plants.*

23. Claim 23 reads:

"A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides together with one or more chitinases; and/or one or more beta-1,3-glucanases in a synergistically effective amount;
said method comprising the steps of preparing a transgenic plant comprising recombinant DNA sequences encoding one or more lytic peptides, which is not lysozyme together with one or more chitinases; and/or one or more beta-1,3-glucanases."

To the Board, claim 23 is not allowable under Articles 84 and 53(b)EPC. The claim is not clear and concise as no identifiable method steps are recited. Rather all ways of obtaining the stated plant are claimed, including "essentially biological processes for producing plants" which would fall under the prohibition of Article 53(b) EPC second part of first half sentence.

Claim 24 has the same introductory clause as Claim 23 except for the expression "which is not lysozyme" but then continues (differences marked in bold):

"...said method comprising the steps of preparing **two or more** transgenic plants comprising recombinant DNA sequences encoding one or more lytic peptides together with one or more chitinases; and/or one or more beta-1,3-glucanases, **and crossing said plants using conventional breeding techniques.**"

In view of this last claim, issues arise as to what process steps are allowable in a claim having regard to the prohibition of granting patents for essentially biological processes.

24. In the phrase "essentially biological process", "biological" has been interpreted sometimes as contrasting with "technical" and sometimes as contrasting with "chemical" or "physical". Given that the trend of developments is that biological processes are becoming better understood and in that sense possibly more technical, while gene technology makes use of natural mechanisms and in that sense is biological, attributing a meaning to the term "essentially biological" in terms of the present technical developments is problematic.

25. To decide whether a process can be defined as an "essentially biological process" requires a value judgment of the extent to which it should be non-biological before it loses the status of "essentially biological process", which value judgement can be arrived at by different approaches.

26. One approach is analogous to that used under Article 52(4) EPC relating to methods of treatment by surgery and therapy. As stated for example in decision T 820/92 (OJ EPO 1995, 113) "in the case of a method involving administration of two or more substances, the question for the purposes of Article 52(4) EPC is not whether the main or even the only reason for carrying out the whole of the claimed method is non-therapeutic. Rather, a method claim falls under the prohibition of Article 52(4) EPC if the administration of one of the substances is a treatment by therapy, and the administration of this substance is a feature of the claim."

27. The consequences of such an approach would be that to be considered as "non essentially biological", the claimed process for producing plants should only comprise clearly identified non-biological process steps and no "essentially biological" steps (whatever uncertainties may be attached to the term). A process involving the crossing of two existing plants such as in claim 24 would not be allowable. This

approach would have the advantage that it would be clear to applicants what steps to mention in a claim.

28. A second approach would be that adopted in decision T 320/87 (OJ EPO 1990, 71) where it was held that whether or not a process is to be considered as "essentially biological" 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 (see point 6 of the reasons). The consequences of such an approach, as discussed in T 356/93 (*loc. cit.*, see point 28 of the reasons), would be 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 does not fall under the exceptions to patentability under Article 53(b) EPC first half sentence." Following such an approach leaves it to the instances of the EPO to assess whether a claim as a whole is directed to an "essentially biological process for the production of plants". Its outcome could be relatively uncertain.

29. Yet another approach would require, for a process for the production of plants to escape the prohibition of Article 53(b) EPC with regard to essentially biological processes, at least one clearly identified "non-biological" process step but allow any number of additional "essentially biological steps" which would be carried into allowability by the "non-biological" process step. The definition given in the proposed EU directive Article 2 No. 2 adopts this approach. The definition is "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection". This approach would be that most favourable to applicants. It is not the approach so far adopted by the boards of appeal.

Microbiological processes and their products: Article 53(b) EPC second sentence

30. Even if a genetically engineered plant variety could also be considered a product of a microbiological process (and decision T 356/93 (loc. cit.) came to the conclusion that this was not so), the question still has to be answered whether taking the original meaning of the prohibition of Article 53(b) EPC as a whole, the genetically engineered variety is closer to the original concept of plant variety or closer to the original concept of a product of a microbiological process. The genetically engineered plant variety bears no relation to what was originally meant by the product of a microbiological process (see points 48 and 49 below for discussion of this), whereas it is virtually indistinguishable in type from conventionally produced plant varieties. For the Board, this leads to the conclusion that genetically engineered varieties are covered by the prohibition of granting patents for plant varieties of Article 53(b) EPC even if they should in some sense be considered as the product of a microbiological process.

The second question to the Enlarged Board of Appeal

31. This question reads:

"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?"

32. The second question specifically deals with one line of argument by the Appellant, which is suitably described as the "more than a single variety" approach. The Appellant is understood to acknowledge that embodiments falling within claim 19 include plant varieties, but to be arguing that the claim is nevertheless permissible despite Article 53(b) EPC because (a) more than one plant variety falls under the claim and/or (b) because the scope of the claim is broad enough to also cover plants which are not plant varieties.

33. This view also corresponds to the view expressed in the literature (e.g. Referral to the Enlarged Board of Appeal in case G 3/95 (OJ EPO 1996, 169); Lange, GRUR Int. 1996, 586; Schatz, GRUR Int. 1997, 588; Straus, GRUR Int. 1998, 1) that the invention being a broad technical contribution capable of being embodied in all sorts of plants, the Appellant was not only entitled to patent protection for this contribution but urgently needed broad patent protection by product claims to plants representing this contribution (see here in particular Straus (loc. cit., page 1, r.h.c., section 2 "... um von dem Alptraum fast völliger Schutzlosigkeit ihrer mehr als bemerkenswerten Erfindungen erlöst zu werden" (... to be saved from the nightmare of virtually complete lack of protection for their more than remarkable inventions)). A parallel was drawn by the present Appellant to the protection available by means of product claims in normal chemistry (see point VI(a) above "...and if technical inventors did not get patent protection for such inventions they were left with nothing at all.").

34. The Board remarks that various aspects of the above mentioned broad technical contribution may be protected in claims of different categories, i.e. in method claims leading to the preparation of the genetically engineered plants, product claims relating to the gene expressing the desired feature, and claims to the vector by which transformation of the plant cells is carried out, none of which according to decision T 356/93 (loc. cit.) falls under an exclusion from patentability. It is, thus, plainly wrong to say that the inventors are deprived of all protection for their technical contribution unless genetically modified plants are patentable.

35. The Board is nonetheless fully aware of the fact that a claim to a genetically modified plant may give the best protection to the technical contribution made by the Appellant, just as product claims are preferred in the chemical field. This need for product claims for plant varieties cannot in itself override an existing prohibition of patenting of the product "plant varieties". It is the generally expressed view that the duty of the judges is to apply and not to create the law (see Smith and Baily "The Modern English Legal System" Second Edition i.a. page 21 "D. Law Reform"; Bergel

"Méthodes du droit, Théorie générale du droit" Deuxième édition, Nos. 49 to 52; Palandt "Bürgerliches Gesetzbuch" 53. Auflage, Seite 8, Rdnr. 49 "Der Richter darf sich über ein Gesetz nicht schon deshalb hinwegsetzen, weil es reformbedürftig oder nicht sachgerecht erscheint" ('The judge cannot disregard a law merely on the ground that it appears to be in need of reform or inappropriate' - translation by board). As put forward by the Appellant (point VI(h) above), this view is in line with the approach of the International Court of Justice of dynamically interpreting the law, but not to the extent of modifying a convention.

36. On a plain reading of the language of Article 53(b) EPC which (in all three official languages) states that patents shall not be granted for plant varieties in the plural, the Board cannot see convincing force in the argument presented by the Appellant (point VI(a) above). To deduce from this wording of Article 53(b) EPC that a patent shall not be granted for a single plant variety but may be granted if its claims cover more than one variety, does not appear to comply with the normal rules of logic.

37. Avoidance of the prohibition of Article 53(b) EPC would then merely mean drafting a claim to a plant with some characteristics of any actual embodiment left unspecified. This would ensure that, at least theoretically, the claim covered potentially more than one variety. The Board would agree that claim 19 covers more than a single variety, and would be allowable if the "more than a single variety" approach were correct, and the answer to question 2 were "yes".

38. Considerable problems are posed by the "more than a single variety" approach.

39. If the answer to the referred question 2 is yes, then any claim to plants in terms broad enough to cover more than a single variety would be permissible under Article 53(b) EPC, irrespective of whether conventional breeding or genetic engineering was used to produce such plants. The existence of Article 53(b) EPC insofar as it refers to plant varieties (and the corresponding provision in the Strasbourg Convention from which Article 53(b) EPC is derived) would thus be hard to explain whether by a

reference to a desire to harmonize with the provisions of the 1961 UPOV convention or otherwise.

40. Taking the "more than a single variety" approach to its logical conclusion, claims of the form "A plant variety as per the deposited sample or varieties derived therefrom" would also cover more than a single variety, and so would be permissible.

41. If, however, the approach is not taken to its logical conclusion, and specific varieties remain unpatentable then the concept that specific embodiments of an invention, namely the actual plant varieties should not be patentable, but that it should nevertheless be possible to have a broad claim to plants whose scope includes all such varieties, is a notion quite alien to patent law in general. It would leave a fundamental anomaly at the heart of patent law as it relates to plants.

42. In relation to animal varieties, in decision T 19/90 (OJ EPO 1990, 476), one of the issues on which the Board of Appeal reversed the Examining Division was in allowing a claim directed to mammals in general into which an oncogenic sequence had been introduced. This claim was clearly broader than a claim to a single variety, and yet the Board sent back the claim for consideration of whether an animal variety was being claimed. The "more than a single variety" approach which would presumably also allow claims to genetically modified animals provided the claim was not limited to a particular animal variety did not occur even as a possibility to the Board deciding T 19/90 (loc. cit.).

Interpretation of Article 53(b) EPC

43. In the Board's opinion, Article 53(b) only needs interpretation if its meaning in the context of its purpose is not clear. It is true that the meaning of the term "plant varieties" has been much discussed in the literature and in earlier decisions. Furthermore three different definitions of the term were given in the UPOV 1961, its revised version of 1991 (in force since April 1998) and in Council Regulation (EC)

No. 2100/94 of 27 July 1994 on Community plant variety rights which last definition is virtually identical to that in UPOV 1991 (see Annexes IV and V). It would not however seem that defining "plant variety" is critical in the present case since it has been agreed by the Appellant that claim 19 includes plant varieties (see point VI(o) above). As for the purpose of Article 53(b) EPC, the Board sees it as being to exclude plant varieties from patent protection. If the Enlarged Board comes to the conclusion that there is need for interpretation, then the intention of the legislators is one of the means of interpretation to be looked at.

Intentions and considerations moving the legislators when introducing Article 53(b) EPC

44. The wording of Article 53(b) EPC goes back to the earlier Strasbourg Convention of 27 November 1963 on the Unification of Certain Points of Substantive Law on Patents for Invention. Little useful contemporary material on the precise considerations or intentions behind the provision can be found either as part of the preparatory material for the Strasbourg Convention whose Article 2(b) was taken over and incorporated into Article 53(b) EPC or as part of that for the European Patent Convention.

45. The only relevant discussion noted by the Board in the preparatory material for the European Patent Convention, relates to the systematic relationship between Articles 52 and 53 EPC, and is set out in Annex III. From the documents cited in this Annex, it appears that the drafters of the EPC quite deliberately chose to put the exclusion of plant and animal varieties of what is now Article 53(b) EPC in a quite different category from the exclusions of what is now Article 52(2) and (4) EPC. Further the material referred to in the discussions (see paragraph 98 cited in Annex III) and the question put to the WIPO representative suggests that compatibility with UPOV 1961 was not the prime purpose of the exclusion, but merely something to be checked incidentally.

46. The following considerations should be taken into account when trying to understand the intentions behind the exclusion:

(a) At the time of the Strasbourg Convention, some states already had adopted national laws on the protection of plant varieties and seeds, and the 1961 UPOV convention had been entered into to harmonize these internationally. No special laws for protecting animal varieties existed. There does not seem to have been any substantial interest in obtaining patents on a Europe-wide basis for plant or animal varieties.

(b) While the existence of a separate protection system for plant varieties on the model sponsored by UPOV was an important reason, it was not the only reason for the legislator to exclude plant varieties from patent protection in the EPC. Thus according to Beier/Straus "Gentechnologie und gewerblicher Rechtsschutz", Ind. Prop. 1986, S. 447 an essential reason for Article 53(b) EPC was that in the light of differences in the laws and of conflicting interests of the European states in this area, consensus on the convention as a whole might have been in jeopardy if this controversial topic had not been excluded.

(c) Patent offices were not equipped to determine whether plant varieties met the criteria of stability or homogeneity for a plant variety, whereas government operated seed research establishments in many countries were so equipped. National laws on plant and seed varieties also made provision for information on stability and homogeneity to be provided subsequent to application, provided periods of grace in which even commercial use of the variety would not be detrimental to novelty, had no requirement for inventive step and usually granted longer periods of protection than was available under ordinary patent law.

(d) No-one seems to have been equipped to examine any form of industrial property right relating to animal varieties, so that the exclusion of animal varieties from protection seems explicable on the basis that no protection should be available under

the EPC in an area for which there was no national provision, and no experience of making available such protection.

(e) The majority of the Contracting States were of the opinion that most biological inventions could not be described sufficiently to be reproducibly put into practice (see *Tetraploide Kamille II* case, GRUR Int. 1996, 1059) and that therefore patent protection was little suited to such inventions which were best left to protection under UPOV.

(f) The laws of the member states relating to patent infringement were not adapted to cope with the problems that patents on self-reproducing biological material (other than microorganisms) might give rise to.

(g) No precise definitions of the term "plant and animal varieties" have been included in the EPC and plant and animal varieties are coupled in a single prohibition.

47. Points (a) to (g) suggest that all problems that the patenting of self-reproducing living organisms at the level of higher plants or animals would pose, were simply to be by-passed by excluding them from patentability under the European Patent Convention. Individual Contracting States might choose to have national laws allowing such patenting, if they had no separate plant variety protection, but nothing was forced on them in this respect.

48. Finally, it should also be kept in mind that more than ten years of scientific progress were necessary after the European Patent Convention was drafted, before it became conceivable that varieties could be isolated with the help of techniques including microbiological steps. It, thus, could not have been the intentions of the legislator to have plant varieties patentable as products of microbiological processes.

49. A view, mentioned in biology textbooks (cf. Stern, *Introductory Plant Biology*, 7th edition 1997 pp. 257-259), had existed that all living matter could be described as

belonging either to the plant or the animal kingdom. Later biologists defined various other kingdoms for different classes of microorganisms (fungi, bacteria). Given that processes involving microorganisms, such as fermentation processes or the production of pharmaceuticals had long been patented, and that these processes were to remain patentable, the "exclusion to the exclusion" of Article 53(b) EPC for microbiological processes and their products appears to have been introduced as a precautionary measure to ensure that the terms "plant" or "animal" were not interpreted so broadly as to cover also yeast, bacteria and other micro-organisms, processes involving these being already at the time of the Strasbourg Convention considered patentable. The Appellant appears to agree that this was the position when the EPC came into force (see point VI(j) above).

50. To the Board it appears that the prohibition of Article 53(b) EPC relating to the patenting of plant and animal varieties and essentially biological processes for the production of plants and animals does not suggest any intention on the part of the legislator that plant or animal varieties should become patentable according to criteria to be developed by the instances of the European Patent Office, merely because advances in knowledge and technological capabilities might make it easier to create new varieties with particular properties. Rather it suggests an intention to exclude varieties from patenting until such time as the legislators reconsider the matter. To expand the "exception to the exception" of Article 53(b) EPC, second half sentence so far as to hollow out and nullify completely the prohibition on the grant of patents for plant and animal varieties, seems to go beyond any legitimate form of interpretation.

The case law of the Boards of Appeal on non-patentability (Article 52 EPC) and exceptions to patentability (Article 53 EPC).

51. Article 52(1) EPC provides that

"(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."

Article 52(2)(3) EPC then goes on to detail things which are not, as such, to be regarded as inventions within the meaning of Article 52(1) EPC, the provisions reading:

"(2) The following in particular shall **not be regarded as inventions** within the meaning of paragraph 1:

- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities **as such**." (Emphasis by the Board)

A comparison between the provisions of Article 52(2)(3) EPC and Article 53(b) EPC

52. The prohibition of Article 53(b) EPC on the grant of patents for plant or animal varieties is in absolute terms, and on the plain wording applies even though the plant or animal variety is an invention, is susceptible of industrial application, is new and does involve an inventive step.

53. The Board considers that the different wording used in Article 53(b) EPC and in Article 52(2) EPC, and the fact that these exceptions from patentability are in different articles was intended to emphasize that there is a difference in legal category between the Article 52(2) EPC exceptions relating to matter which as such

is not regarded as an invention, and the Article 53(b) EPC exceptions for which patents are not to be granted, even though they could be regarded as inventions (see also discussions of legislator set out in Annex III).

54. That the categories listed in Article 52(2) EPC, such as computer programs are only not inventions "as such", has allowed the development of a jurisprudence (see for example decisions T 208/84 (OJ EPO 1987, 14) and T 26/86 (OJ EPO 1988, 19) allowing patents where the matter incapable of being an invention "as such" is used as part of a combination where the combination as a whole can be considered as an invention.

55. The Board observes, to draw a direct parallel to the "combination" matter, that Claim 19 is not directed to any form of "combination" that avoids the prohibition on the grant of patents for plant varieties. As a theoretical example it might perhaps be argued in relation to a claim to a mixture of two different plant varieties in a particular ratio, which produced a mutually beneficial effect on growth when planted together, that such a claim was not directed to genetically altered new and inventive plant varieties "as such" and so avoided the prohibition of Article 53(b) EPC.

56. A situation of this kind could be compared to the situation in decision T 49/83 (OJ EPO 1984, 112) where a claim to chemically treated seed was found allowable. For the Board the essence of that decision lies in the passages of point 4 of that decision quoted below:

"4.... By contrast, the innovation claimed here does not lie within the sphere of plant breeding, which is concerned with the genetic modification of plants. Rather, it acts on the propagating material by means of chemical agents in order to make it resistant to agricultural chemicals. The new parameter for the propagating material, namely treatment with an oxime derivative, is not a criterion which can be characteristic of a plant variety as far as the protection of varieties is concerned.

.....Conversely, it is immaterial to the question of patentability that the propagating material which is treated can also be, or is primarily, a plant variety..."

For that decision the result would have been the same if a specific variety had been explicitly recited in the claim. In such a claim, the chemically treated plant variety is not claimed "as such" but only when chemically treated in a particular way. The invention lay in the chemical treatment. Claim 19 of the present application is in a quite different category because the invention does lie in the sphere of plant breeding and is concerned with a criterion which can be characteristic of a plant for the purposes of plant variety protection.

57. For this reason the Board sees no useful analogy between the legal status under the EPC of items listed in Article 52(2) EPC and the legal status under the EPC of plant varieties.

A comparison between the provisions of Article 52(4) EPC and Article 53(b) EPC.

58. Article 52(4) EPC provides that:

"Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

59. The methods referred to in Article 52(4) EPC thus potentially fall into the legal category of inventions but are excluded from patentability by being deemed not to be susceptible of industrial application. As legal categories the exceptions of Article 52(4) EPC and Article 53 EPC are closer to each other than either is to the exceptions of Article 52(2) EPC, which are not as such even regarded as being inventions.

60. The prohibition on the grant of patents for methods of treatment is, thus, indirect in the sense that by Article 52(4) EPC such methods are not to be considered as susceptible of industrial application. On the contrary, by Article 53(b) EPC, a direct prohibition on the grant of patents for plant or animal varieties exists even in cases where these fulfill all the requirements for patentability. Prima facie, there thus appears an even stronger case not to allow any claims which could conflict with the direct prohibition of Article 53(b) EPC on the patenting of plant and animal varieties.

61. In the Referral to the Enlarged Board of Appeal in case G 3/95 (*loc. cit.*, see point 3.6), the President of the EPO remarked that one essential historical reason for the exclusion of patentability of plant varieties was the prohibition of double protection in Article 2(1) of the UPOV and that Article 53(b) EPC was to be seen as a corollary of said prohibition, that the intentions of the legislator were thus different from those leading to the exclusion under Article 52(4) EPC, and that therefore, it was unwarranted to develop the same rules of jurisprudence in both cases.

62. For the Board, the fact that the purpose of Article 53(b) EPC is different from that of Article 52(4) EPC does not necessarily lead to the conclusion that for one Article its plain wording is to be disregarded but for the other article attention is to be paid to the wording.

63. Therefore, it seems of relevance to look at the jurisprudence of the Boards of Appeal in cases relating to Article 52(4) EPC where a method was claimed which, although not expressly directed to a method of treatment of the human body, nonetheless amounted to such a treatment, when read with skill in the light of the specification and applying a "substantive approach" (see points 10 to 16 above. In such cases (T 290/86 (OJ EPO 1992, 414), T 780/89 (OJ EPO 1993, 440), T 116/85 (OJ EPO 1989, 13), T 144/83 (OJ EPO 1986, 301)) the Boards found the claimed methods unpatentable for the very reasons that they could also serve as therapeutic methods of treatment of the human body which were barred from patentability under Article 52(4) EPC.

Interpretation taking into account subsequent practice

64. The Appellant submitted that the Vienna Convention (Article 31(3)) provided clear authority that subsequent practice should be used to interpret a Treaty. Furthermore, it was established international public law that the subsequent practice did not necessarily need to be directly under the Treaty which had to be interpreted but could be demonstrated by reference to other international treaties, even unratified, as long as there was a demonstrated link to a provision which had to be interpreted. The Community Patent Convention, the TRIPS agreement and the draft EC directive related directly to Article 53(b) EPC, and, thus, were subsequent practice to be taken into account.

65. As explained by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 064) the Vienna Convention is not directly applicable to the EPC, but its principles can be referred to as they embody recognized international practice. The Board will, thus, review the submissions presented in this context.

TRIPS

66. The Contracting States of the European Patent Convention are all members of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (TRIPS) approved in Geneva on 15 December 1993. The European Patent Organisation is not a party to the treaty.

67. Article 27 (Patentable Subject Matter) of TRIPS provides:

"1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.....

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans and animals;

(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreements Establishing the WTO."

68. In view of the exceptions permitted under Article 27.3(b), the Board cannot see any possibility of conflict between the Contracting States obligations under TRIPS, and the provisions of the EPC whichever of the above suggested possible interpretations of Article 53(b) EPC is adopted.

UPOV

69. The UPOV 1991 has now entered into force. It permits, but does not require, member states to have both patent and plant variety protection for plants. Again the Board cannot see any possibility of conflict between the Contracting States obligations under UPOV 1991 (or whatever earlier UPOV convention Contracting States of the EPC may be members of), and the provisions of the EPC whichever of the above suggested possible interpretations of Article 53(b) EPC is adopted.

Council Regulation (EU) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights

70. Excerpts of this regulation considered by the Board to be relevant are set out in Annex IV to this decision. The recitals make clear that the definition of "plant variety" "is not intended to alter definitions which were earlier established..., nor to interfere with or exclude from application laws governing the protectability of products,

including plants and plant material, or processes under such other industrial property rights".

71. Thus, nothing in this regulation provides any clear indication that the EPC or its interpretation should be changed in a particular manner.

The European Patent Convention and International Treaties

72. Not all Contracting States of the European Patent Convention are members of the EU, and the EPO is not an organ of the EU. Further the European route via the EPO is just one way that national patents can be obtained in the Contracting States. To meet their obligations to the EU or under TRIPS or other international treaties, it would be sufficient for Contracting States to modify their national patent laws without modifying the EPC. Given that most patent applications in the plant field in Europe are filed at the EPO, it would be extremely regrettable if the EPC was not adapted to permit obtaining as broad a protection as could be obtained via a national route but failure to adapt the EPC would not appear to be a breach of any direct obligation of any treaty provisions.

Proposed DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL on the legal protection of biotechnological inventions

73. On 12 May 1998 the European Parliament approved the above directive as published in the EU Official Journal of 23 March 1998. With its fifty-six recitals, compared to three recitals for the EPC, it clearly is, and is intended to be, a landmark in the development of patent law in Europe.

74. The proposed directive is addressed to EU Member States, which do not coincide with the Contracting States to the European Patent Convention. Article 1(1) provides that EU Member States shall protect biotechnological inventions under national patent law. Member States shall, if necessary, adjust their national patent

law to take account of the provisions of this Directive. Article 17 provides that this directive shall enter into force on the day of its publication in the Official Journal of the European Communities. Article 15(1) provides that Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than...[within two years of its publication in the Official Journal of the European Communities] They shall immediately inform the Commission thereof.

75. These articles raise the immediate question of the extent that the directive can be looked to at all as regard present practice of the EPO, as opposed to for a change in future EPO practice.

76. Chapter I: Patentability, with its Articles 1 to 6 gives definitions of plant variety, biological material, and lays down what shall not be patentable, what shall be patentable and what shall be considered unpatentable. In Chapter II: Scope of protection, with its Articles 8 to 11, provisions of major importance are laid down, including in Article 11 derogations in favour of farmers using the product of his harvest for reproduction or propagation by him on his own farm. In Chapter III: Compulsory cross-licensing, Article 12 lays down conditions for a compulsory licence under a patent in favour of breeders who cannot acquire or exploit a plant variety right without infringing a prior patent. To the Board there appear here to be major changes to existing laws, but it is not clear whether the new legal regime is to apply to all patents in force in EU Member States whenever granted, or only to those granted from some future date with the old legal regime still applying to patents granted earlier than this date, nor precisely when the new legal regime is to supplant the old legal regime.

77. Given these uncertainties, and the fact that the proposed directive does not expressly state that EU Member States shall also take measures to revise inter alia the European Patent Convention, and that not all Contracting States of the EPC are

EU Member States, treating the proposed directive as evidence of any agreed subsequent practice under the EPC seems problematical.

78. It seems open for discussion whether a revision of the European Patent Convention pursuant to Article 172 EPC by a Conference of the Contracting States is not called for to achieve legal certainty. In view of Article 164(2) EPC that in the case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail, it appears questionable whether a mere amendment by the Administrative Council of the EPO of the Implementing Regulations pursuant to its power under Article 33(1)(b) EPC could serve to change the meaning of the Articles of the European Patent Convention, or bind the courts of Contracting States who may be called to interpret the EPC for the purposes of national proceedings.

The third question to the Enlarged Board of Appeal

79. The question reads:

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

80. The present practice of the European Patent Office is to ignore the provisions of Article 64(2) EPC reading:

"If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process"

when examining the allowability of process claims with respect to Articles 52 to 57 and 83 EPC, on the basis that this is a provision addressed not to patent offices but only to courts in the Contracting States concerned with considering alleged

infringements. National legislation in these States has re-enacted this provision of the EPC or has made it directly binding.

81. It is quite common that a new process is developed to produce a known product. This known product, when directly obtained by the new process, falls, by Article 64(2) EPC, under the protection conferred by the patent on the new process. The drafters of the EPC saw no conflict here with the requirement under Articles 52(1) and 54 EPC that patents shall be granted for inventions that are new. The extension of the protection conferred on the patented process to cover a known product, was not considered a violation of the provisions of Articles 52 and 54 EPC.

82. Likewise, the Board would see no conflict between on the one hand the plant variety indirectly enjoying patent protection as the direct product of a process under Article 64(2) EPC and on the other hand the plant variety as such not being patentable under Article 53(b) EPC.

83. The only case of which the Board is aware of national courts considering a national provision equivalent to Article 64(2) EPC in relation to plant varieties is an action for revocation of a patent decided on appeal by the Bundesgericht in Switzerland (see *Tetraploide Kamille II* case, *loc. cit.*). The reasoning is complex and partly based on features specific to the Swiss legislation but what is relevant to the present case is that the Bundesgericht saw no conflict between the protection given to a claim to a process for making a plant variety extending to the plant variety so produced on the one hand and the Swiss equivalent to Article 53(b) EPC on the other hand, but a specific claim to a plant variety made by this process was considered invalid as contravening the Swiss equivalent to Article 53(b) EPC. The Bundesgericht thus disagreed with the view of the first instance that a process claim providing the "derived" protection to the product is not allowable for the reason that the provisions for an exclusion of patentability have priority over the provision of derived scope of protection. The Bundesgericht came to a different conclusion for the reason that the view of the first instance contradicted the position taken by the

Swiss Bundesrat in its comment of 16 August 1989 to the amendment of the patent law (BBl. 1989 III 232 ff), which said that the derived product protection applies even if the product as such is not patentable because it is excluded from patent protection by a special prescription in the law.

84. Such derived protection also appears to be accepted in Benkard/Bruchhausen, Patentgesetz, 9th edition 1993, who say in the last sentence of marginal note 13 on § 2 (which includes the German equivalent to Article 53(b)) that "with the exclusion of essentially biological processes for the production of plant varieties, the intention is to prevent protection of the variety itself via § 9 second sentence number 3 (the German equivalent of Article 64(2) EPC).

85. Some of the arguments put forward by the Appellant in relation to the discussions under the Community Patent Convention (CPC) (see point VI(i) above) would appear to challenge the present EPO practice of disregarding Article 64(2) EPC when considering the allowability of process claims (see Guidelines for examination, C-III, 4.7b). To the Board, these arguments appear to be beside the point. The proposed addition to the equivalent in the CPC of Article 64(2) EPC of the words "insofar as such product is not a plant or animal variety excluded from patent protection under Article 53 of the European patent convention" would have been directed to infringement courts and would have explicitly precluded such courts from considering a plant variety as being the direct product of a process. From the fact that the proposal was dropped, it follows only that the possibility was kept open under the CPC, as it is under the EPC, for infringement courts to find that a plant variety is the direct product of a patented process and as such enjoys protection. To the Board this appears a question that has to be answered in each particular case by the court concerned.

86. Again that, as argued by the appellant, there were proposals in the preparatory stages of UPOV 1991 for a provision that a plant variety could not be considered to be an infringement of a patent, and that these proposals were dropped merely

means to the Board that infringement courts of EPC Contracting States who have ratified UPOV 1991 and for whom it is in force are not explicitly precluded from considering a plant variety an infringement as a direct product of a patented process. However, no definite conclusions can be drawn from this as to the meaning of Article 53(b) EPC.

87. On the coming into force of the proposed EU directive, its Chapter II (Articles 8 to 11) would appear to require the national laws of EU member states to be revised, as this Chapter II seems to give far more extensive rights than Article 64(2) EPC, while at the same time introducing new possibilities for obtaining compulsory licences. But the Board considers that, like Article 64(2) EPC, these articles would be a matter purely for courts considering infringement and the relevant licensing authorities, and are not to be taken into account when a patent office considers compliance with the provisions of Articles 52 to 57 and 83 EPC, or national equivalents.

88. The Board's position is that method claims for the manufacture of plants shall not be examined on their patentability in the light of Article 64(2) EPC. Then applicants in the field of plant breeding by recombinant-DNA-technique have, in addition to all of the forms of protection cited above (see point 34 above), protection for plants produced by the method as long as they are direct products of the method claimed.

The fourth question to the Enlarged Board of Appeal

89. The question reads:

"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 processes for the production of plants, which provision doesn't apply to microbiological processes or the products thereof?"

90. It is based on a possible approach suggested in relation to animal varieties in decision T 19/90 (loc. cit.) at the end of point 4.8:

"...This would also presuppose that Article 53(b) EPC applied at all in respect of animals which are genetically manipulated, given that neither the drafters of the Strasbourg Convention nor those of the EPC could envisage this possibility."

91. Genetically engineered plant varieties could also not have been envisaged by the drafters of the EPC. While it might be difficult in some cases to distinguish them technically in type from conventionally bred plant varieties, they could be considered to be a different legal category. By treating the exception of Article 53(b) EPC as limited to those types of plant and animal varieties and essentially biological processes which were conceivable at the time of drafting, one could boldly conclude that the general rule of patentability applies to all new types conceived since Article 53(b) EPC was enacted, including the new type of genetically engineered plant varieties.

92. In favour of coming to such a conclusion is the fact that this would meet the interests of the inventors and firms active in this field. Apart from the provision of Article 53(b) EPC, the European Patent Convention is already suited to deal with genetic engineering as applied to plant varieties. But, for the Board, there appears no reason why the mere fact of being derived by genetic engineering should give the producers of such plant varieties a privileged position relative to breeders of plant varieties which meet all the requirements of Article 52(1) EPC but have not been arrived at by genetic engineering.

93. Against coming to such a conclusion are the facts that it would be to go beyond the role traditionally allocated to judges and the role allocated to a judicial tribunal under an international treaty. It is not the normal function of judges to override existing prohibitions in the law even in response to the field of application of the law changing as a result of major developments such as gene technology. This is a

matter for the legislator. If, on the other hand, it is seen as making provision for a situation not foreseen by the original European Patent Convention then it would amount to a creation of the Convention, namely the Boards of Appeal, which can only act within the powers given it by the convention, extending the scope of the Convention beyond that originally agreed. This, however, is a matter for a conference of the Contracting States pursuant to Article 172(1) EPC.

94. Furthermore, allowing patentability for new types of plants conceived since Article 53(b) EPC was enacted, appears not to be consistent with such subsequent practice as is evidenced in international treaties and the EU legislation. UPOV 1991 and the Community Regulation (CR) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights (see Article 13.5 cited in Annex IV) provide for protection of plant varieties produced by genetic engineering, by providing protection not only to an original plant variety but also for essentially derived varieties. The EPC provides protection for processes which are not essentially biological, and for plants which do not possess the characteristics of plant varieties. The legislator might thus be of the opinion that enough had already been done.

95. The following article and recitals of the EC Biotechnology Directive which was accepted in the EC Parliament on 12 May 1998 appear relevant in the context of the present question:

Article 4

"1. The following shall not be patentable:

(a) plant and animal varieties,

(b) ...

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety"

Recital 29:

"Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;"

Recital 30:

"Whereas the concept "plant variety" is defined by the law protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties;"

Recital 31:

"Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;"

Recital 32:

"Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a genetic engineering process"

96. From these quotations the most natural deduction is that the drafters of the Directive intended and the EC Parliament approved that in all cases where the technical situation is such that a concept of genetic engineering is the invention which can be applied to more than one variety the resulting products shall be patentable, even if they are plant varieties. This would lead to the conclusion that the

"more than a single variety approach" dealt with in points 32 to 41 is the approach to plant claims most compatible with the Directive. This reduces paragraph 4.1(a) of the directive and recital (32) to minimal significance, the purpose possibly being to ensure compatibility with the derogation from patentability of Article 92 of Regulation (EC) No. 2100/94 (see Annex IV).

97. On the other hand, it could be considered that Article 4.2 of the directive is satisfied by permitting process claims. The technical teaching of an invention concerning plants or animals that is not confined to a particular plant or animal variety, could logically be considered to lie in a generally applicable process. The direct and indirect results of this process would still have protection under Articles 8 to 11 of the directive, though a material having the same characteristics but produced by a different process would not be covered. This view would leave the substantive approach above discussed as the correct approach to plant claims also under the directive, and would allow substantial significance to be given to Article 4.1(a) and recital (32).

Order

For these reasons it is decided that:

The following questions are referred to the Enlarged Board of Appeal for decision:

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?

Annex I

Technical background to the invention:

1. The necessity to adapt plants to the need of mankind has been recognized for thousands of years. Until the last decade, this adaptation was mostly achieved by cross-breeding plants of the same species with different properties: it could, thus, be envisaged to cross-breed a tomato plant which produces large tomatoes with a tomato plant, the tomatoes of which ripen early. Then, these specific plants amongst the progeny which had acquired and were able to stably transfer to their own progeny the beneficial properties of both parents would be selected: in the above illustrative example, tomato plants, the tomatoes of which are large and ripen early.

2. The intrinsic features of this process called cross- breeding are as follows:

- properties may only be exchanged between plants which naturally breed: thus, for example, the colour property of a chrysanthemum cannot be transferred to a petunia because these two plants do not breed in nature.

- properties from other living entities than plants (animals, bacteria, fungi, etc...) cannot be transferred to plants.

- the time necessary to obtain the desired progeny is measured in terms of years.

3. In the early fifties, molecular biology started developing quite independently from the efforts invested by plant breeders in obtaining plants suitable to the needs of mankind. It then became fully apparent that the characteristics of living entities were the visible consequences of metabolic reactions within the living cells, these reactions being carried out by proteins called enzymes, the synthesis of which was initially dependent on a molecule called DNA. Otherwise stated, the DNA comprises

units, the genes, the expression of which most often results in enzymes being produced and, thus, ultimately, in the observed characteristics.

4. Up until the early seventies, the molecular biologists focused on finding out the chemical structure and organisation of DNA in different organisms. Most of the investigations were initially carried out on bacterial genomes which are simpler than mammalian or plant genomes by a factor of 10 to 100.

5. In the early seventies, a new technique was developed which was going to change the relationship of man to its environment. It became possible to transfer the DNA between unrelated living entities: for example, from a mammalian cell to a bacterium and vice versa. At the end of the decade, the expression of the foreign DNA in its novel living environment was also achieved. The very first experiments involved the transfer and expression of foreign genes in micro-organisms or animal cells in culture. Plant cells in culture (plant cells separated from each other in a liquid medium) were not so much in use for three reasons:

- techniques had not yet been fully developed to force the plant cells to let foreign DNA enter because plant cells have a wall which is difficult to penetrate.

- The plant's DNA information necessary to allow the expression of the foreign DNA was badly characterized if at all.

- Difficulties existed in regenerating plant cells in culture into "real plants".

6. However, it was only a matter of a few years before plant cells also became potential recipients for foreign genes and potential expressers of such genes. It became known how to avoid the cell wall barrier and how to regenerate efficiently plant cells into plants. A new way had thus been found to adapt the plants to the needs of mankind.

7. The intrinsic features of this new process called "plant genetic engineering" are as follows:

- a property can be acquired by a plant completely independently from its ability of breeding with the initial "owner" of this property. For example, plant cells can be made resistant to the antibiotic G418, a property which initially belonged to some micro-organisms.

- a beneficial property from one organism can in principle be transferred to any and all plants (vegetables, flowers, trees...) in the form of DNA which these plants can then express and transmit to their progeny.

- the time necessary to make a transgenic plant is in principle measured in terms of months.

8. The invention as described in the patent application takes advantage of these new developments. Plants are isolated which possess the ability to kill or inhibit the growth of pathogens (insects, fungi...) because they carry in their genomes foreign genes, the expression of which results in the production of lytic peptides and hydrolytic enzymes which possess an anti-pathogenically effective activity:

- Examples 6 and 7 describe the isolation of the genes, the expression of which results in an anti-pathogenically effective activity, in a form which the plant will accept and express.

- Examples 8 A - T describe the transfer of these genes into various plant cells: tobacco, carrot sunflower, maize...

- Example 8 U describes how to recognize which plant cells have accepted and expressed the foreign DNA.

- Example 8 V describes the regeneration of transgenic plants from the transformed plant cells.

Annex II

A short glossary of recombinant DNA technology:

The definitions provided below are taken from "Biotechnology made simple; a glossary of recombinant DNA and hybridoma technology", 1983; PJB publication; 18-20 Hill Rise, Richmond Surrey, and from "Engels, J., Glossary: Gene technology, IUPAC 1987". The words appearing in italics in anyone of the definitions are also defined in this glossary. The number of the page where the defined word appears for the first time in the patent application is given between brackets, as well as words belonging to the same family as the defined word (when applicable).

alleles: two *genes* which control the expression of the same character in different ways, e.g. the alleles of the lac gene (fermentation of lactose) are lac⁺ (able to ferment lactose) and lac⁻ (unable to ferment lactose).

amino acids: the building blocks of *protein*. There are 20 main amino acids, each specified by a different arrangement of three adjacent *DNA nucleotides*, which are linked together in a specific order to form a characteristic protein; (amino acid sequence, page 2).

chimaera: a recombinant *DNA* molecule consisting of various fragments from more than one organism; (chimeric gene, page 22).

chromosome: a thread like structure, composed largely of *DNA* and *protein* found in the nucleus of every animal or plant cell.

clone: a population of genetically identical cells derived from the multiplication of a single cell; (page 15).

code: the complete set of codons specifying the various amino-acids; (page 15, genetic code).

complementary DNA: a DNA copy of *messenger RNA*, used for *cloning* DNA (cDNA) and as a probe in hybridisation studies;(page 14).

to digest: (page 15 ,see below, *restriction enzyme*)

DNA (deoxyribonucleic acid): the basic molecular component of the genetic (hereditary) material. Consists of a large number of deoxyribonucleotides linked together to form a long strand. Usually two such strands are linked together parallel to each other and coiled into a helix; (page 2).

enzyme: a *protein* which acts as a catalyst of a biochemical reaction i.e. which speeds up the rate of the reaction; (page 2).

expression (of a gene): the manifestation by a cell of the *protein* coded for by a specific *gene*; (page 2; example: the cell becomes resistant to an antibiotic because it expresses the protein capable of degrading said antibiotic).

expression cassette: a *DNA* fragment containing all of the elements necessary for the *expression of a gene*; (page 15; an example of such an element is a promoter).

gene: a section of *DNA* which codes for a specific *polypeptide*. About one million *genes* could be contained on a one metre length of *DNA*; (page 14).

genome: the full complement of *chromosomes* found in each nucleus of a given species. The genetic constitution of a cell as opposed to its physical characteristics i.e. its *phenotype* which is the physical manifestation of the cell's genetic material; (page 15).

genotype: the set of *genes* possessed by a cell.

homologous: of *chromosomes* or chromosome segments that are identical with respect to their constituent genetic loci and their visible structure.

homozygote: a cell or organism having the same *allele* at a given locus on *homologous chromosomes*; (page 6).

inducer: an effector molecule responsible for the induction of *enzyme* synthesis;(inducible: page 2, induction: page 20).

intron: an intervening section of *DNA* occurring in the middle of a *gene* which does not code for an *amino acid* in the *gene* product. The precursor RNA of the intron is excised and is therefore not *transcribed* into *mRNA* nor *translated* into *protein*;(page 15).

linker: a small fragment of synthetic *DNA* that has a *restriction site* useful for *gene* splicing;(page 17).

ligase: an *enzyme* which joins together two sequences of *DNA*;(page 15, ligation).

lysis: the disruption of a cell membrane allowing the cell contents to escape; (page 2, lytic).

lysozyme: class of *enzymes* that destroy or weaken the cell wall through hydrolysis of the polymers of *amino acids* and amino sugars present in the wall, leading to rupture and death of the *protoplasts*; (page 3).

messenger RNA (mRNA): the RNA molecule that conveys from the *DNA*, the information that is to be translated into the structure of a particular *protein*.

nucleotide: compound formed from one molecule of each of a pentose, of phosphoric acid, and of a nitrogen containing base (purine or pyrimidine). Nucleotides are the building blocks of nucleic acids (*DNA*, *RNA*).

peptide: a compound formed of two or more amino acids; (page 2).

phenotype: the physical manifestation of a cell's genetic material as opposed to the set of *genes* possessed by it (*genotype*; see above).

plasmid: an extra *chromosomal* genetic element consisting of a circular duplex of *DNA* which can replicate independently of chromosomal *DNA*. Used in *gene* transfer, i.e. as a *vector*; (page 14;).

point mutation: a mutation involving a chemical change in only one single *nucleotide* (also called base); (page 15, single base mutation;).

primer: a *DNA* strand used as a starting point for the synthesis of *complementary DNA* from *mRNA* by *reverse transcriptase*; (page 15).

promoter: a recognition site on a *DNA* strand to which *RNA polymerase* binds, thereby initiating *transcription*; (page 14).

protein: the functional or structural component of a cell composed of a linear polymer of *amino acids* joined together by peptide bonds. The precise sequence of amino acids in a specific protein is determined by the sequence of *nucleotides* in the *DNA* which is then transcribed into *RNA* and thence translated into protein in the ribosome. The *E. coli* cells is composed of 3000 or more proteins, all of which can be synthesized simultaneously in precise molar ratios in a matter of seconds;(page 6).

protoplast: a cell without a wall; (page 22).

recombinant DNA: the hybrid *DNA* produced by joining pieces from different sources; (page 6).

restriction site: the cleavage sites of restriction site endonucleases; (page 15; EcoRI site).

restriction enzyme: an enzyme that cleaves (digests) *DNA* at endonuclease sequence-specific sites thereby creating double-stranded breaks.

T-DNA: portion of the *Ti plasmid* that is integrated into the *genome* of the infected plant cell; (page 16).

Ti plasmid: *plasmid* from the bacterium *Agrobacterium tumefaciens* often responsible for crown-gall tumour induction in plants. Used as a basis for the construction of *cloning vectors* for plant cells.

template: the *DNA* single strand complementary to a nascent *RNA* or *DNA* strand which serves to specify the *nucleotide* sequence of the nascent strand; (page 15).

transcription: the synthesis of *mRNA*, made up of a particular sequence of *nucleotides*, by matching with *DNA*, made up of a corresponding sequence of *nucleotides*.

transformation: a mechanism of genetic transfer whereby *DNA* extracted from a donor strain is able to induce permanent genetic changes in a recipient strain with respect to those characters in which the two strains differ; (page 15).

translation: synthesis of a *polypeptide* chain, made up of a particular sequence of amino-acids, by matching with an *RNA* molecule made up of a corresponding sequence of *nucleotides*.

vector: the vehicle by means of which DNA fragments can be incorporated into a host organism. *Plasmids* may be used as vectors; (page 14).

Annex III

Historical documentation relating to the EPC:

Discussions that took place at the inter-governmental conference for the setting up of a European system for the grant of patents.

1. These discussions took place when the predecessors of present Articles 52 and 53 were numbered Articles 9 and 10 of the April 1971 draft, with Article 10 already being worded identically to present Article 53 EPC, but Article 9 reading:

"Article 9

Patentable inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) Inventions within the meaning of paragraph 1 shall in particular exclude:

(a) scientific and mathematical theories;

(b) the mere discovery of materials occurring in nature;

(c) purely aesthetic creations,

(d) schemes, rules or methods of doing business, performing purely mental acts or playing games;

(e) methods for treatment of the human [or animal] body by surgery or therapy, as well as diagnostic methods;

[(f) mere presentations of information;]

[(g) computer programmes]."

2. In relation to the 4th session of the inter-governmental conference which took place in Luxembourg between 20 and 28 April 1971 Dokument BR/125 d/71 at

page 8 (BR/125 d/71 zat/MP/K/cs) contains the following report: (translation by the Board from the original German).

"SECOND PART

SUBSTANTIVE PATENT LAW

CHAPTER I

Patentability

Article 9 (Patentable inventions)

Article 10 (Exceptions to patentability)

16. The conference asked working group I, to check Article 9 subsection (2) again - and in particular the words in square brackets - and to take account in particular the submissions by the interested circles when doing so. The working group I should further check the relationship between Article 9 subsection (2), in which is listed what is not to count as an invention, and Article 10, which lists the exceptions to patentability.

In particular, the question was raised, whether Article 10 subsection (b) was compatible with the provisions of the Strasbourg [sic] Convention for the protection of plant varieties. In the view of some delegations, it could be deduced from the present version of Article 10, that plant and animal varieties are inventions, even though they are excluded from patentability; according to the view of other delegations this conclusion cannot be drawn from the wording of Article 10."

3. In the report on the 9th session of working group I, (document BR/135 d71), taking place in Luxembourg between 12th and 22 October 1971, at page 52 (BR/135 d/71 arx/MS/K/bm) there then appears the following (translation from the German by the Board):

"Article 10 - Exceptions to patentability

98. The working group investigated the question raised in the conference whether Article 10 subsection (b) was compatible with the Paris Convention for the protection of plant varieties [i.e. UPOV 1961- annotation by Board]. The representative of WIPO told the working party that in the opinion of the "Plant Variety Union" the two conventions were compatible.

99. The British delegation then suggested altering subsection (b), so that it would be confined to reading: "for plant or animal varieties", giving as reason that the meaning of the words "for essentially biological processes" was not clear, and that in their view there was no justification, expressly to exclude in the Convention other biological processes, not intended for the treatment of the human body. This proposal was not supported by other delegations.

Relationship between Article 9(2) and Article 10

Two delegations suggested that subsection (b) of Article 9 be included in Article 10 subsection (2). For an applicant the two groups of exceptions produced the same result.

Countering this, some other delegations made a distinction between Article 9 subsection (2) and Article 10 subsection (b); in their opinion Article 9 subsection (2) was dealing with things that were not inventions, whereas Article 10 subsection (b) was dealing with inventions, which were however expressly excluded. Further it was deemed desirable to stick to the wording of the Strasbourg convention.

The above suggestion was not adopted.

Annex IV

Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community Plant Variety Rights (Excerpts)

Whereas plant varieties pose specific problems as regards the industrial property regime which may be applicable;

Whereas industrial property regimes for plant varieties have not been harmonized at Community level and therefore continue to be regulated by the legislation of the Member States, the content of which is not uniform;

Whereas in such circumstances it is appropriate to create a Community regime which, although co-existing with national regimes, allows for the grant of industrial property rights valid throughout the Community;

...

Whereas the system must also have regard to developments in plant breeding techniques including biotechnology; whereas in order to stimulate the breeding and development of new varieties, there should be improved protection compared with the present situation for all plant breeders without, however, unjustifiably impairing access to protection generally or in the case of certain breeding techniques;

Whereas varieties of all botanical genera and species should be protectable;

....

Whereas it is important to provide for a definition of a plant variety, in order to ensure the proper functioning of the system;

Whereas this definition is not intended to alter definitions which may have been established in the field of intellectual property rights, especially the patent field, nor to interfere with or exclude from application laws governing the protectability of products, including plants and plant material, or processes under such other industrial property rights;

Whereas it is however highly desirable to have a common definition in both fields; whereas therefore appropriate efforts at international level should be supported to reach such a common definition;

....

Whereas in order to stimulate plant breeding, the system basically confirms the internationally accepted rule of free access to protected varieties for the development therefrom, and exploitation of new varieties;

Whereas in certain cases where a new variety, although distinct, is essentially derived from the initial variety, a certain form of dependency from the holder of the latter should be created;

...

Whereas compulsory licensing should also be provided for in certain circumstances in the public interest, which may include the need to supply the market with material offering certain features, or to maintain the incentive for continued breeding of improved varieties,

...

Whereas it is indispensable to examine whether and to what extent the conditions for the protection accorded in other industrial property systems, such as patents, should

be adapted or otherwise modified for consistency with the Community plant variety rights system; whereas this, where necessary, should be laid down in balanced rules by additional Community law;

Article 1

Community plant variety rights

A system of Community plant variety rights is hereby established as the sole and exclusive form of Community industrial property rights for plant varieties.

Article 3

National property rights for plant varieties

This Regulation shall be without prejudice to the right of Member States to grant national property rights for plant varieties, subject to the provisions of Article 92(1).

Article 5

Object of Community plant variety rights

1. Varieties of all botanical genera and species, including *inter alia*, hybrids between genera or species, may form the object of Community plant variety rights.

2. For the purpose of this Regulation, 'variety' shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety are fully met, can be:

! defined by the expression of the characteristics that results 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.

3. A plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred to hereinafter as 'variety constituents'.

4. The expression of the characteristics referred to in paragraph 2, first indent, may be either invariable or variable between variety constituents of the same kind provided that also the level of variation results from the genotype or combination of genotypes.

Article 13

Rights of the holder of a Community plant variety right and prohibited acts

1.

2.

3.

4.

5. The provisions of paragraphs 1 to 4 shall also apply in relation to:

(a) varieties which are essentially derived from the variety in respect of which the Community plant variety right has been granted, where this variety is not itself an essentially derived variety;

(b) varieties which are not distinct in accordance with the provisions of Article 7 from the protected variety; and

(c) varieties whose production requires repeated use of the protected variety.

6. For the purposes of paragraph 5(a), a variety shall be deemed to be essentially derived from another variety, referred to hereinafter as the 'initial variety' when:

(a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety;

(b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and

(c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety.

...

Article 92

Cumulative protection prohibited

1. Any variety which is the subject matter of a Community plant variety shall not be the subject of a national plant variety right or any patent for that variety. Any rights granted contrary to the first sentence shall be ineffective.

2. Where the holder has been granted another right as referred to in paragraph 1 for the same variety prior to grant of the Community plant variety right, he shall be unable to invoke the rights conferred by such protection for the variety for as long as the Community plant variety right remains effective.

Annex V

On the definition of the term "plant variety":

1. There is no generally agreed definition of plant varieties available from scientific textbooks. The European Patent Convention does not provide any definition of the term. At the time the European Patent Convention was drafted, a definition of plant varieties had been provided in the 1961 version of the UPOV Convention for the purpose of establishing the legal framework in which plant breeders may enjoy a right of protection. Another such definition is provided in the 1991 revised version of said Convention, which is now in force.

These two definitions are:

1961 UPOV Convention:

Article 2(2): For the purpose of this Convention, the word "variety" applies to any cultivar, clone, line stock or hybrid which is capable of cultivation and which satisfies the provisions of subparagraphs (1) (c) and (d) of Article 6.

Article 6(1)(c): The new variety must be sufficiently homogeneous having regard to the particular features of its sexual reproduction or vegetative propagation.

Article 6(1)(d): The new variety must be stable in its essential characteristics, that is to say, it must remain true to its description after repeated reproduction or propagation or, where the breeder has defined a particular cycle of reproduction or multiplication, at the end of each cycle.

Article 6 subparagraphs (1)(c) and (d) defines the properties of a **new** variety. Thus, novelty as defined in Article 6(1)(a) 1961 UPOV Convention is also an attribute of a plant grouping eligible for protection.

1991 UPOV Convention

Article 1(vi): "variety" means a plant grouping within a single botanical taxon of the lowest known 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 conditions for the grant of the breeder's right with regard to the criteria to be satisfied are further stated in **Article 5(1):**

The breeder's right shall be granted where the variety is

- (i) new
- (ii) distinct
- (iii) uniform and
- (iv) stable

Thus, the definition of "plant variety" provided in the 1961 UPOV Convention is almost synonymous with "variety which would be eligible for protection" under said Convention.

2. In the 1991 revised version of the Convention, the distinction between "varieties" and "protectable varieties" is made clearer by the use of the words "irrespective of whether the conditions for the grant of a breeder's right are fully met" in the preamble of the definition of the term "variety". In order to establish an identity for a variety, the criteria of distinctness, uniformity and stability are used (second and third paragraphs of Article 1(vi). These criteria also belong to the definition of a "protectable variety" (Article 5(1)(ii) to (iv)), which are then probably applied at a higher level of stringency.

* Case pending under Ref. No. G 1/98.

** Annexes not published.