Enlarged Board of Appeal, 9 December 2010, Essentially Biological Process
Broccoli I (G 2/07) & Tomato I (G 1/08)

Brassica oleracea

PATENT LAW

Excluded essentially biological process: process containing sexually crossing

- **A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC**.

It must be concluded that the legislator's intention was to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time.
These conventional methods included in particular those (relevant for the present referrals) based on the sexual crossing of plants (i.e. of their whole genomes) deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s).

Excluded also if process of sexually crossing contains technical step enabling or assisting sexual crossing

- **Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selec-tion, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.**

Hence, in more general terms, the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC.

Non-excluded; process containing step which by itself introduces or modifies a trait in the genome of the plant produced

- **If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.**

that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability. Therefore, such a process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.
The above applies only where such additional step is performed within the steps of sexually crossing and selection, independently from their number of repetitions. Otherwise the exclusion of sexual crossing and selection processes from patentability under Article 53(b) EPC could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from such crossing and selection process.
Any such additional technical steps which are performed either before or after the process of crossing and selection should therefore be ignored when determining whether or not the process is excluded from patentability under Article 53(b) EPC. For the previous or subsequent steps per se patent protection is available.
This is the case, for example, for genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.
As a result this means that, while the presence in a claim of one feature which could be characterised as biological does not necessarily result in the claimed process as a whole being excluded from patentability under Article 53(b) EPC (see 6.2 above), this does not apply where the process includes sexual crossing and selection.

Nature of additional technical step irrelevant

- **In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in**

nature or whether the essence of the invention lies in it.

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Enlarged Board of Appeal EPO, 9 December 2010
(P. Messerli, B. Günzel, R. Freimuth, L. Galligani, K. Härmand, K. Klett, S. Perryman)
Case Number: G 0001/08
D E C I S I O N of the Enlarged Board of Appeal
of 9 December 2010
Appellant I (Patent Proprietor): State of Israel - Ministry of Agriculture, Volcani Research Center, P.O. Box 6, 50250 Beit Dagan (IL)
Representative: Vossius & Partner, Siebertstraße 4, 81675 München (DE)
Appellant II (Opponent): Unilever N.V., Weena 455, 3013 AL Rotterdam (NL)
Representative: Tjon, Hon Kong Guno, Unilever Patent Group, Olivier van Noortlaan 120, 3133 AT Vlaardingen (NL)
Referring Decision: Interlocutory decision of the Technical Board of Appeal 3.3.04 dated 4 April 2008 in case T 1242/06.
Composition of the Board: Chairman: P. Messerli, Members: B. Günzel, R. Freimuth, L. Galligani, K. Härmand, K. Klett, S. Perryman.

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Summary of Facts and Submissions

By decision of 21 April 2008 the Enlarged Board decided to consider the points of law referred to it by Technical Board of Appeal 3.3.04 in case T 83/05 (G 2/07) and in case T 1242/06 (G 1/08) in consolidated proceedings.

I. Referral G 2/07

1. The referred questions

By interlocutory decision T 83/05 dated 22 May 2007, Technical Board of Appeal 3.3.04 referred the following questions to the Enlarged Board of Appeal:

"1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?

2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?"

2. The subject-matter of appeal proceedings T 83/05

The proceedings before the referring Board concern appeals against the decision of the opposition division, according to which European patent No. 1 069 819 was maintained in amended form. During the oral proceedings before the referring Board, the patent proprietor (respondent in the appeal proceedings) submitted a new main request and an auxiliary request. Claim 1 of the main request reads as follows:

"1. A method for the production of Brassica oleracea with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3- methylsulfinylpropyl glucosinolates, or both, which comprises:

a) crossing wild Brassica oleracea species selected from the group consisting of Brassica villosa and Brassica drepanensis with broccoli double haploid breeding lines;

b) selecting hybrids with levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines;

c) backcrossing and selecting plants with the genetic combination encoding the expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both; and

d) selecting a broccoli line with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinlates [sic], or both, capable of causing a strong induction of phase II enzymes, wherein molecular markers are used in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes."

Claim 1 of the auxiliary request differs from claim 1 of the main request by the addition of the step of "deriving broccoli double haploid breeding lines" as the first step of the claimed method.

3. The referring decision

3.1 Impact of the referred questions on the outcome of the appeal proceedings

According to the referring Board, in the proceedings before it the referred important points of law arise because no other grounds of opposition prejudice the requested maintenance of the patent in suit in amended form. In particular, the requirements of Article 83 EPC are met, since seeds of the plant species B. villosa and B. drepanensis were available to the public, and so were techniques to obtain double haploid lines of broccoli. Methods of backcrossing were generally known in the art, and selecting hybrids with glucosinolate levels elevated above that initially found in broccoli double haploid breeding lines would not cause any problem to a skilled person. As for the molecular markers to be used in steps (b) and (c) of the method of claim 1 of each request, before the priority date of the patent in suit methods to produce molecular markers that segregate with a desired trait were commonly known in the art and were used in the context of Brassica species. Even though some effort is necessary to design the required specific markers, this nonetheless is a standard method which does not amount to undue burden. The referring Board also acknowledges inventive step. Selecting the wild B. oleracea species B. villosa and B. drepanensis for the purpose of crossing these with broccoli lines in order to increase the level of 4-MSB GSL or 3-MSP GSL in broccoli was not obvious. On the one hand, broccoli cultivars were known to produce relatively high levels of 4- MSB GSL and thus already contained the correct combination of alleles to produce this glucosinolate. On the other hand, B. drepanensis did not produce 4-MSB GSL and B. villosa and B. drepanensis were known to be closely related. A skilled person would therefore not have expected from the prior art that such an increase could be achieved by crossing the broccoli lines with the wild species B. villosa or B. drepanensis.

3.2 Exclusion of essentially biological processes for the production of plants (Article 53(b) EPC)

The referring Board sets out the legislative history of Article 53(b) EPC and the relevant case law thereto, in particular decision T 320/87 (OJ EPO 1990, 71). With respect to the legislative history of Article 53(b) EPC 1973, the referring Board concludes that the drafters of the provision regarded "biological" as being in opposition to "technical" and that, by deliberately choosing the adverb "essentially" to replace the narrower term "purely", they considered plant breeding processes based on selection and hybridisation to fall under the exclusionary provision even if secondary features of the processes were characterised by the use of technical devices.

3.3 Rule 23b(5) EPC 1973

The referring Board sets out the legislative history of Rule 23b(5) EPC 1973 and Article 2(2) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter "Biotech Directive"). In the view of the Board, the wording of Article 2(2) Biotech Directive and Rule 23b(5) EPC

1973 is somewhat contradictory and difficult to understand. On the one hand, only processes which consist entirely of natural phenomena are considered to be essentially biological processes for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena. This appears to be selfcontradictory to some extent since the systematic crossing and selection carried out in traditional plant breeding would not occur in nature without the intervention of man. Particularly when taking into account the adverb "entirely", the wording of Rule 23b(5) EPC 1973 aims at a very narrow construction of the process exclusion contained in Article 53(b) EPC 1973. The referring Board interprets Rule 23b(5) EPC 1973 as meaning that a process which, apart from "natural phenomena" (which appear to cover crossing and selection by way of a legal fiction), contains an additional feature of a technical nature would be outside the ambit of the process exclusion. This was not the approach adopted by the boards of appeal before the introduction of Rule 23b(5) EPC 1973. The referring Board then voices its doubts as to the applicability of Rule 23b(5) EPC 1973 on the basis of Article 164(2) EPC 1973, according to which the provisions of the Convention shall prevail in case of conflict with provisions of the Implementing Regulations. Furthermore, in its view it may be argued that the competence of the Administrative Council to amend the Implementing Regulations according to Article 33(1)(b) EPC 1973 does not extend to core issues of substantive patent law, so that the introduction of provisions determining the boundaries of patentable subject-matter is ultra vires. A third issue is whether Rule 23b(5) EPC 1973 can be applied to applications pending at the date of its entry into force.

3.4 Relevance of determining the correct approach for the appeal case

The respondent argued that there were at least three levels of human intervention which brought the claimed invention outside the exclusion from patentability of Article 53(b) EPC 1973:

- First, the use of molecular markers in steps (b) and (c) of the claimed process was a technical step requiring removal and in vitro analysis of plant tissues.
- Second, the claimed invention required the use of a non-natural starting material, i.e. a double haploid strain, which was made by the technical steps described by the respondents.
- Third, the wild Brassica strains mentioned in step (a) of the claimed process grew in remote geographical locations and were not likely to hybridise with broccoli breeding lines unless specifically brought into contact with them by human intervention.

According to the referring Board, the approach adopted by Rule 23b(5) EPC 1973 would lead to the conclusion that at least the first feature relied upon by the respondent would be sufficient to bring the claimed process outside Article 53(b) EPC 1973, since the use of such molecular markers involves subjecting plant material to an analytical laboratory process.

If, however, the approach adopted in previous decisions T 320/87 (OJ EPO 1990, 71) and T 356/93 (OJ EPO 1995, 545) were still the correct one, none of the features relied upon by the respondent would make the claimed method escape the process exclusion of Article 53(b) EPC 1973. The use of molecular markers such as DNA markers is a well-known step in the selection of plants with desired characteristics. Methods to discover and produce molecular markers that segregate with a desired trait were commonly known in the art and had already been used in the context of Brassica species. This feature is therefore not able to contribute anything beyond a trivial level to the claimed invention.

Double haploid breeding lines are, as such, well known in plant breeding, and techniques to obtain them in broccoli were publicly available before the priority date. The derivation of such breeding lines can therefore not be regarded as being the essence of the claimed invention or as contributing anything beyond a trivial level to it. The argument that wild Brassica strains are unlikely to hybridise with broccoli breeding lines in nature does not, in the Board's view, assist the respondent in the context of Article 53(b) EPC 1973, irrespective of whether the approach adopted by Rule 23b(5) EPC 1973 is followed or not. Even the most traditional forms of plant breeding consisting entirely of crossing and selection are unlikely to occur in nature as such, but are characterised by some form of human intervention.

II. Referral G 1/08

1. The referred questions

By interlocutory decision T 1242/06 dated 4 April 2008, Technical Board of Appeal 3.3.04 referred the following questions to the Enlarged Board of Appeal:

"1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

2. If question 1 is answered in the negative, does a nonmicrobiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?"

2. The subject-matter of appeal proceedings T 1242/06

The proceedings before the referring Board concern both parties' appeals against the decision of the opposition division, according to which European patent No. 1 211 926 was maintained in amended form on the basis of auxiliary request IIIb. The patent concerns a

method for breeding tomato plants that produce tomatoes with reduced fruit water content. Claim 1 of the main request, which also underlies the referring decision, was rejected by the opposition division as being excluded from patentability by Article 53(b) and Rule 23b(5) EPC 1973.

Claim 1 of the main request reads as follows:

"A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of: crossing at least one Lycopersicon esculentum plant with a Lycopersicon spp. to produce hybrid seed; collecting the first generation of hybrid seeds; growing plants from the first generation of hybrid seeds; pollinating the plants of the most recent hybrid generation; collecting the seeds produced by the most recent hybrid generation; growing plants from the seeds of the most recent hybrid generation; allowing fruit to remain on the vine past the point of normal ripening; and screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin."

Claim 1 of auxiliary request I contains inter alia the additional feature of "selecting plants with tomato fruits having an increased dry weight percentage".

3. The referring decision

3.1 Relevance of determining the correct approach to Article 53(b), Rule 26(5) EPC for the appeal case

Since the opposition division did not examine the method claims of the main request with respect to any other ground of opposition, the referring Board does not consider it possible to deal with the claims of the main request (or to remit the case to the department of first instance) before taking a decision on the sole reason for which they were considered unallowable. If the approach adopted in decision T 320/87 (supra, points 4 to 10 of the Reasons) were still the correct one, the subject-matter of claim 1 of appellant I's (patent proprietor's) main request and of auxiliary request 1 (filed in the appeal proceedings) would not escape the exclusion. The arguments put forward by appellant I to show that the claimed method requires a high level of human intervention cannot alter the conclusion that the essence of the claimed method is "classical" plant breeding technology. Neither the necessity of an interspecific cross nor the choice of an unusual selection criterion nor the existence of technical steps such as weighing and drying take the claimed method outside the realm of classical plant breeding technology, which frequently uses corresponding elements of human intervention. In the view of appellant I, the exclusion under Rule 26(5) EPC should only apply if the claimed steps reflect and correspond to phenomena which could occur in nature without human intervention. This is not the case for the claimed method. First, the interspecies crossing between L. esculentum and a wild tomato species requires special intervention in order to reach a reliably fertile offspring and would not take place in nature since generally individuals belonging to separate species are not capable of interbreeding. Second, selection for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin would not occur in nature. The referring Board states that, if the legal interpretation of Article 53(b) and Rule 26(5) EPC advocated by appellant I were to be followed, it would consider at least the first of appellant I's two arguments to be persuasive, due to the absence of any evidence in the file showing that said interspecies crossing is possible without human intervention. Furthermore, appellant I suggests that in the light of Rule 26(5) EPC, a plant breeding process based on crossing and selection does not fall under Article 53(b) EPC if it contains, as a further step or as part of the steps of crossing and selection, an additional feature of a technical nature. In the present case, the plant breeder has to allow the fruit to remain on the vine past the point of normal ripening. Moreover, claim 1 of the first auxiliary request refers to the selection of plants with tomato fruits having an increased dry weight percentage, which implies that fruit samples are first weighed fresh, then dried in an oven and weighed again in their dried state. The referring Board does not consider the step of allowing the fruits to remain on the vine past the point of ripening to qualify as technical, since it is characterised by an abstention from human intervention. It accepts, however, that the determination of the dry weight percentage of fruits is an implicit feature of claim 1 of auxiliary request I and as such constitutes a technical step. The allowability of this claim thus depends on the merits of appellant I's supplementary line of argument, i.e. on the suggestion that a plant breeding process based on crossing and selection escapes Article 53(b) EPC if it contains, as part of the steps of crossing and selection, an additional feature of a technical nature.

3.2 Meaning of Rule 26(5) EPC

According to the referring Board the meaning of Rule 26(5) EPC is difficult to understand in so far as it mentions crossing and selection as examples of natural phenomena. On the one hand, the systematic crossing and selection carried out in traditional plant breeding would not occur in nature without the intervention of man. On the other hand, it is hardly conceivable that the terms "crossing" and "selection" in Rule 26(5) EPC are intended not to refer to plant breeding at all but only to purely natural events taking place without human control. The expression "processes for the production of plants" (German version: "Verfahren zur Züchtung von Pflanzen", French version: "procédés ... d'obtention de végétaux") in Article 53(b) EPC implies at least some kind of human intervention. Furthermore, it would have the awkward consequence of restricting the scope of the exclusion to subject-matter which, owing to its complete lack of technical character, does not qualify as an invention anyway, so that there would be no need to exclude it from patentability by an explicit provision. The referring Board therefore takes the view that the mere fact that a claimed process requires some kind of human intervention is not, even in the light of Rule 26(5) EPC, sufficient to take the process outside the patentability exclusion. The crucial issue, according to the referring Board, is rather to determine what kind of human intervention is required.

III. The course of the proceedings before the Enlarged Board

In both referrals the Enlarged Board invited the President of the EPO to comment in writing on the points of law referred to the Enlarged Board and also issued an invitation for third parties to file comments. The President of the EPO commented in writing on referral G 2/07 and later declared that she had no additional comments on referral G 1/08. Furthermore, numerous third parties submitted comments in writing. By decision of 21 April 2008 the Enlarged Board decided to consider the points of law referred to it by Technical Board of Appeal 3.3.04 in case T 83/05 (G 2/07) and in case T 1242/06 (G 1/08) in consolidated proceedings. On 27 January 2010 the Enlarged Board sent out a summons to attend oral proceedings and on 16 June 2010 a communication drawing attention to a number of issues that appeared of significance for discussion in the oral proceedings. Oral proceedings were held on 20 July 2010. At the end of the oral proceedings, the Chairman announced that the Enlarged Board would give its decision in writing.

IV. The submissions of the parties

All parties to the present referral proceedings have made comprehensive submissions. In view of the volume of these submissions, they are summarized briefly. For further details of the parties' submissions, reference is made to the file. The submissions, before the Enlarged Board, of Appellants I and II in appeal case T 83/05 were essentially made by reference to the EPC 1973. Their submissions will therefore be reproduced here by reference to the EPC 1973, it being common ground that in the EPC 2000 the provisions referred to were amended only by renumbering the corresponding provisions of the Implementing Regulations.

1. Appellant I (Opponent I) in appeal case T 83/05

With regard to Article 53(b) EPC 1973 there is no indication that a general freedom to operate for breeders was intended. The reasons for the exception were not so much ethical or economic concerns as based on the fact that at the time of drafting the relevant text, breeding results regarding plants and animals were considered not patentable because they lacked repeatability. Hence, the legislator may have perceived an antinomy between "technical" processes and "biological" processes in the sense of non-technical, natural processes. However, as a result of the technological development having taken place in the meantime and the terms "biological" and "technical" no longer being antonyms, extension of the area of patentable subject-matter is a normal consequence.

To interpret Rule 23b(5) EPC 1973 to the effect that it excepts all processes that consist only of crossing and selection steps, regardless of how technical these steps are, takes Rule 23b(5), second halfsentence, EPC 1973 out of the context of the first half-sentence and of Article 53(b) EPC 1973. It would also result in a clear conflict with Rule 23c(c) EPC 1973, which preserves patentability for technical processes. It appears appropriate to construe the terms "crossing" and "selection" as only referring to natural phenomena. For instance, sexual crossing by undirected pollen transfer would in general be a natural phenomenon and "selection" a natural selection in the sense of Darwin's theories. Under these prerequisites processes which are only based on crossing and selection are in general patentable as long as they represent a technical teaching. For this, the essence or character of the invention considered as a whole must be determined. The mere addition of a technical step to an otherwise non-technical process does not ipso facto change the essence or character of that process. A technical step which has no impact on the essence of the invention can be seen as severable and can be neglected for the evaluation of the exclusion under Article 53(b) EPC 1973. The process remaining after separating the technical feature would remain entirely biological, "non-technical" and completely consisting of natural phenomena. As far as the disputed patent (i.e. the "broccoli patent", addition by the Enlarged Board) is concerned, although some of the parental lines were double-haploid as a consequence of non-natural techniques having been used for their production, the crossing steps are natural since they do not comprise cell-fusion or other artificial crossing techniques. The selection of plants with an increased content of the desired glucosinolates is based on marker-assisted selection. In consequence, the claimed process consists entirely of crossing and selection steps. Article 53(b) EPC 1973 excludes only methods of breeding which, when seen as a whole, do not represent a reproducible, technical teaching, because they are based in their essence on natural phenomena such as sexual crossing and natural selection. With regard to marker-assisted breeding, the disclosure of the marker needs to be specific, substantial and credible to allow the person skilled in the art to carry out the invention without undue burden. Otherwise it is not capable of conveying technical character. The assessment whether or not a breeding process represents a technical teaching should be performed as defined by the established case law of the EPO Boards of Appeal and has to focus especially on the criteria of enablement and reproducibility, since enablement and reproducibility are at least intrinsic prerequisites for a technical character. The process should be considered outside of Article 53(b) EPC 1973 if it represents - when seen as a whole - a reproducible, technical teaching, even if such process consists completely of biological steps. The fact that a process could occur in nature is not a contradiction to its technical character.

2. Appellant II (Opponent II) in appeal case T 83/05

Rule 23b(5) EPC 1973 is compatible with the true meaning of Article 53(b) EPC 1973 and with existing case law. The introduction of Rule 23b(5) EPC 1973 was clearly intended to be in keeping with the Convention. Rule 23b(5) EPC 1973 is not intended to be a conclusive definition of "essentially biological processes" but rather a definition of a reference. The clear and unambiguous test under Rule 23b(5) EPC 1973 and Article 53(b) EPC 1973 is as follows:

- if the essential elements of the process are natural phenomena, then the process is excluded under Article 53(b) EPC 1973,
- if the essential elements of the process are not natural phenomena, then it is not excluded.

It must therefore first be established which steps of the process are natural phenomena and which steps involve human intervention. Then it must be determined whether those steps involving human intervention are essential to the process. For that, the criteria laid down in existing case law, particularly T 320/87 (supra) and T 356/93 (supra), should be applied. A process must have at least one essential technical step which cannot be carried out without human intervention and which has a decisive impact on the final result. Question 1 cannot be answered with a clear "yes" or "no". If the technical step to which reference is made in question 1 is an essential technical step, which cannot be carried out without human intervention and has a decisive impact on the final result, then it makes the method escape the exclusion of Article 53(b) EPC 1973. Otherwise it does not. This is also the response to question 2. Since Rule 23b(5) EPC 1973 refers to crossing and selection as examples of "natural phenomena", that term as used in Rule 23b(5) EPC 1973 must be understood to refer to process steps which involve at least a minimum of human intervention. This also applies because in the absence of technical character, purely natural phenomena are already excluded under Article 52 EPC 1973. The term "natural phenomena" being intended to include traditional plant breeding methods, the meaning attributed to that term must therefore clearly encompass traditional breeding processes and must also accommodate the evolution over time of the notion of "traditional". Yesterday's traditional breeding methods were based mainly on phenotypic characterization. In today's "traditional" plant breeding methods, plants are evaluated through genetic analysis of the DNA from a piece of leaf and the plants that do not contain the gene of interest are discarded. Both kinds of methods have in common that whilst the modern kind of human intervention facilitates the achievement of the desired result, it does not have a decisive impact on that result. Hence, the term "natural phenomena" as recited in Rule 23b(5) EPC 1973 does not mean only steps of crossing and selection which reflect and correspond to phenomena which occur in nature without human intervention. Rather, "natural phenomena" means technical steps which are characterized in that the decisive steps are natural processes, human intervention having no decisive impact on the result achieved.

The Appellant also commented on referral G 1/08 suggesting that the answer to the first question put to the Enlarged Board of Appeal should be: "A non-microbiological process for the production of plants consisting of steps of crossing and selecting plants, falls under the exclusion of Article 53(b) EPC (1973, addition by the Enlarged Board) if these steps reflect and correspond to phenomena which occur in nature without human intervention, or if the steps of human intervention have no decisive impact on the result achieved". That answer also provides the answers to question 2 and 3. In particular, with respect to question 2, the presence of an additional feature of a technical nature, as part of any of these steps of crossing and selection, does not in itself take the process out of the exclusion of Article 53(b) EPC 1973. With respect to question 3, whether the additional technical feature contributes something to the claimed invention beyond a trivial level is decisive in determining whether the process escapes the exclusion under Article 53(b) EPC 1973. If the human intervention is the essence of the process, then the exclusion is avoided.

3. Respondent (Patent Proprietor) in appeal case T 83/05

The only purpose of also excluding "essentially biological processes for the production of plants" from patentability in Article 53(b) EPC 1973 was the avoidance of double protection for plant varieties (via a process claim). The degree of the required impact of the technical feature is not defined in the Travaux Préparatoires and no reasons are provided why any technical feature should not be sufficient. A broad interpretation of the exclusion as adopted in T 320/87 (supra) violates the general principle that exclusions are to be interpreted narrowly. Rule 26(5) EPC must also be interpreted narrowly. The rule is a definition, which must be used for interpreting Article 53(b) EPC. The exclusion applies only to methods for generating a plant variety as they were used in the sixties, based entirely on natural phenomena such as sexual crossing and natural selection. All substantive submissions made which come to the conclusion that question 1 as referred to the Enlarged Board of Appeal in T 83/05 should be answered in the negative, in particular those requiring that a technical feature should be a feature which cannot be omitted without losing the desired effect, add further requirements to the definition of Rule 26(5) EPC and Article 2(2) Biotech Directive. The definition of Rule 26(5) EPC and Article 2(2) Biotech Directive cannot be reinterpreted to this extent by the boards of appeal. For practical purposes it will be very difficult, if not impossible, to determine whether a feature of a technical nature is absolutely required for carrying out a method for producing a plant or not. The concern voiced that a completely irrelevant technical feature could be used to render patentable a method for producing plants which otherwise would not be patentable is not justified since such methods must meet all requirements of the EPC. In particular, they must be sufficiently disclosed as well as novel and inventive. Hence, a claim directed to a trivial method for producing plants characterized by a superfluous technical feature will not be granted. As a consequence, question 1 of referral decision T 83/05 should be answered in the affirmative. However, should the Enlarged Board of Appeal not answer the first question in the affirmative, the answer to the second question should be that a non microbiological plant production process is not excluded from patent protection under Article 53(b) EPC if it contains a step of a technical nature that affects the genotype of the plants produced by the process.

4. Appellant I (Patent Proprietor) in appeal case T 1242/06

The primary intention of the legislator when excluding essentially biological processes from patentability was the avoidance of double protection for plant varieties. On the other hand there should be no loopholes in the protection. Furthermore, plant production processes which are clearly of a technical nature because the process requires more than only applying biological forces, should be patentable, as can be derived from the legal history of the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg Patent Convention (SPC)) and the EPC. Therefore, the term "essentially biological processes for the production of plants" refers to processes for breeding plant varieties, and the term "technical process" as used in Rule 27(c) EPC refers to those breeding processes which at least in part do not rely on biological forces or phenomena. As with the assessment of whether or not an invention is technical in the sense of Article 52(1)-(3) EPC, the decision as to whether a plant breeding process is essentially biological cannot be made by using terms such as "trivial", "conventional" or "traditional" which introduce a time-dependence into the debate and thus require consideration of the prior art concerned.

By Rule 26(5) EPC the legislator effected an adjustment to the interpretation of Article 53(b) EPC. Even if any case law decision taken before entry into force of the rule had a different result than the interpretation to be given to Rule 26(5) EPC, that would not be a case of a conflict between the said rule and the article. The definition given in Rule 26(5) EPC is only a necessary condition, but not a necessary and sufficient one. Accordingly, a method which, in addition to natural phenomena, contains at least one further step of a different nature, escapes the prohibition. Such a strict approach also seems to be better in terms of legal certainty and practicability.

There is no reason to require that the technical (i.e. non-natural phenomena) feature must be essential in order to bring the process out of the prohibition zone. Crossing and selection are covered by the exclusion to the extent that they are "natural phenomena".

Non-natural crossing and selection steps are those that are carried out with a technical element based on human influence or based on a manestablished criterion in contrast to a natural force. In particular, if the selection criterion is set up by man, irrespective of the means by which man actually selects, this is not a natural phenomenon. Likewise, the step of choosing non-natural breeding partners falls outside the realm of "natural phenomena". As regards selection, only selection for an advantage for survival in nature occurs naturally. The examination of whether a claimed plant breeding process is a natural one can be performed along the following lines: in the case of crossing, it would require that one can expect that fertile offspring would result from the interaction of two starting lines in the field under natural conditions. With respect to selection, the suggested approach would require assessing whether the selection criterion applied in the claimed method would mean an increased fitness under natural conditions as compared to the pedigree lines, so that a natural selection can be expected. Questions 1 and 2 should be answered in the affirmative. Question 3 should be answered in the sense that only breeding methods are to be excluded, the direct products of which are specific, individual plant varieties.

5. Appellant II (Opponent) in appeal case T 1242/06

Rule 26(5) EPC should be interpreted in accordance with the existing case law relating to Article 53(b) EPC. There is no basis in the legislative history for the argument that the legislator intended to depart radically from this case law. According to such harmonized interpretation, in a breeding process the terms "crossing" and "selection" are to be understood as natural phenomena when directed to "the sexual crossing of whole genomes" and to "selection after such a cross of whole genomes, perhaps followed by further crossing". The word "entirely" in Rule 26(5) EPC is meant to make breeding processes patentable which include technical steps which go beyond that. One example could be a process whereby a new plant is produced by inserting a novel gene. Saying that any breeding process which comprises a technical step, regardless of its impact, would make it non-natural and take the process outside the exclusion of Article 53(b) EPC, would make that article obsolete, since in fact, all selection in plant breeding is carried out by man and is therefore nonnatural. The overriding purpose of plant breeders is to produce a plant with a new combination of traits or, more precisely, a new combination of genes. Nevertheless, the genetic make-up of a cross is determined by the underlying inherently biological and random process of meiosis, during which the exact distribution of genes occurs and selection by breeders does not directly determine the genetic make-up of a cross. Plant breeders crossing plants use various technical aids or technical steps during screening. For the crossing of plants technical aids are used by breeders to overcome the barriers that have prevented the particular cross occurring in nature, for instance because the respective plants flower at different times, because the pollen may not have the right surface active proteins to enter the stigma, or because the flowers of one parent are inaccessible for natural pollination by the other parent. Breeders have thought of many ingenious ways to overcome natural barriers in the last two hundred years. The handbook for breeders "Hybridisation of crop plants" (filed by the appellant II as document D 47 in the proceedings before the Enlarged Board) has a long list of technical steps on pages 145, 147, 149 to 153. Such crossing is, however, still a natural phenomenon, since the inherently random process of meiosis determines whether or not a plant is created with the right combination of genes. With respect to "selection", although the breeder, by deciding which plants he will use for the next (back-)cross and which not, can increase the chance of a successful cross, whether or not a plant is created with the right combination of genes is still determined by meiosis. Allowing general plant claims

obtained from traditional methods such as back-crossing would disregard the fact that breeding based on the crossing of whole genomes is in principle non-reproducible and therefore not a teaching which can be generalized across other plants. The "resemblance-to-nature-criterion" underlying question 1 in decision T 1242/96 contradicts existing case law according to which the total effect of human intervention is decisive and not its resemblance to nature. It would also be impossible to answer as it assumes we have a full knowledge of what occurs in nature (in fact) or could occur (in theory) and it would render Article 53(b) EPC pointless. As a result, questions 1 and 2 of referral T 1242/96 should be answered in the negative and question 3 should be answered in the affirmative, twice.

V. The parties' final requests

At the end of the oral proceedings before the Enlarged Board all parties concluded their pleadings by handing to the Enlarged Board, again in writing, their final requests for the proceedings before the Enlarged Board. These requests are annexed to the Minutes of the public oral proceedings before the Enlarged Board of Appeal of 20 July 2010 as Annexes A to E. For the details of the requests, reference is made to the file.

VI. The President's submissions

The legislator is entitled to effect provisions of a substantive nature in the Implementing Regulations. The limit of such power is indirectly enshrined in Article 164(2) EPC. Under that Article, the Implementing Regulations must be interpreted in the light of the Convention. Even if it is considered that Rule 26(5) EPC changed, i.e. narrowed the scope of application of Article 53(b) EPC, no legitimate expectations or acquired rights can be affected since Rule 26(5) EPC remains within the framework of what could have been decided with respect to Article 53(b) EPC by the departments entrusted with the procedure. This is demonstrated by the discussion of possible approaches as developed in decision T 1054/96 (OJ EPO 1998, 511). As to substance, notwithstanding the intrinsic ambiguities of the wording of Rule 26(5) EPC, the approach to be adopted should be based on a dynamic and harmonised interpretation of the process exclusion under Article 53(b) EPC. A process for the production of plants is essentially biological if it consists entirely of natural phenomena, these being understood as those which are uncontrollable and/or occur without human intervention, including the methods used by conventional plant breeders, such as sexual crossing or natural selection. Given that, for example, selection may be technical and cannot always be considered a "natural" phenomenon, crossing and selection must be construed as constituting possible examples of natural phenomena only if they are of a nontechnical nature.

The term "essentially biological" comprises both a quantitative and a qualitative element. The quantitative element requires at least one non-biological feature, whilst the qualitative element requires that such a feature have a genuine technical effect. The Article should be interpreted to the effect that the process exclusion does cover processes which comprise, in addition to natural phenomena, features of an insubstantial or insignificant technical nature. In order to escape the process exclusion, an additional feature of a technical nature should have a technical effect, provided by human intervention, on the process as such or on the product obtained therefrom. If the non biological feature can be omitted without losing the desired effect, the process is not patentable.

VII. The amici curiae

Numerous amicus curiae briefs were filed by professional representatives, interest groups, plant breeders and seed producing associations and firms, scientists, by groups concerned with the ethical and economic impact of the subject-matters involved and by private persons. The submissions made reflect divergent views which were also expressed by the parties, as described in the summary of the parties' submissions given above. In particular, many submissions supported the view that in a process based on crossing and selection, i.e. a conventional breeding process, only a technical step having a decisive impact on the final result should make a claimed process escape the exclusion under Article 53(b) EPC. Others supported the approach that, by analogy with the computer-implemented inventions approach, the presence of any technical step should suffice to make the claimed process escape the exclusion. Finding a right approach to what deserved patent protection was rather a matter for inventive step. A third group of amicus curiae briefs raised objections against the patenting of the kind of technologies in question here based on general ethical and economic concerns about the patenting of plants and animals in general and of those produced by conventional plant breeding methods in particular.

Reasons for the Decision

1. Admissibility of the referrals

Both referring decisions set out in detail why, in the Board's view, an answer to the referred questions is necessary for the decisions on the appeals. In decision T 83/05, the referring Board gives extensive reasons why the remaining patentability requirements, such as the absence of added subject-matter, sufficiency of disclosure, entitlement to priority, novelty and inventive step would be fulfilled for the claims on file. Furthermore, the decision also sets out why the outcome of the appeal case hinges on the interpretation of the process exclusion contained in Article 53(b) EPC 1973. In decision T 1242/06, the referring Board explains why the referred questions are in its view decisive for the decision on whether the subject-matter of the main request is excluded from patentability. Furthermore, since none of the remaining opposition grounds was dealt with in the decision of the opposition division with respect to the main request, the case would have to be remitted to the opposition division if the subject-matter of the main request were not excluded from patentability. These explanations of the referring Board sufficiently demonstrate that answers to the referred issues are necessary for the Board to decide on the appeals before it on a correct interpretation of the law. The referrals are therefore admissible, irrespective of whether an answer is

actually required on all aspects which the referred questions might in theory be seen as embracing.

2. Applicable law

2.1 EPC 1973 vs. EPC 2000

Referral G 2/07 was made before the entry into force of the EPC 2000 and was based on the EPC 1973. Referral G 1/08 was made after the entry into force of the EPC 2000 and was based on the EPC 2000. Both referrals concern the application and interpretation of Article 53(b) EPC/EPC 1973. According to Article 1(1) of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (OJ EPO 2001, Special Edition No 4, 139), Article 53 EPC in its revised version shall apply to European patents granted at the time of entry into force of the EPC 2000. The patents underlying both referrals having been granted before that date, the answer to both referrals will have to be given applying Article 53 EPC. As a consequence, in accordance with Article 2 of the Decision of the Administrative Council of 7 December 2006 amending the Implementing Regulations to the European Patent Convention 2000 (OJ EPO 2007, Special Edition No 1, 89), the Implementing Regulations to the EPC 2000 pertaining to Article 53 EPC are to be applied to the presently referred questions. This concerns in particular Rule 26(5) EPC, formerly Rule 23b(5) EPC 1973, which defines the term "essentially biological process...".

2.2 Article 33(1)(b) EPC and substantive patent law

In decision T 83/05 the referring Board raises the issue of whether the competence of the Administrative Council to amend the Implementing Regulations according to Article 33(1)(b) EPC 1973 extends to core issues of substantive patent law. If not, the introduction of provisions determining the boundaries of patentable subject-matter was ultra vires (point 58 of the Reasons). It does not emerge clearly from the referring decision what would be, in the view of the referring Board, the legal consequence of Rule 23b(5) EPC 1973, now Rule 26(5) EPC, being ultra vires. However, in the preceding passage, point 57 of the Reasons, the referring Board deals with the potential outcome that the interpretation to be adopted for Rule 23b(5) EPC 1973 runs counter to Article 53(b) EPC / EPC 1973 and cannot be followed in view of Article 164(2) EPC. Therefore it is likely that the underlying position of the referring Board in point 58 of the Reasons is that a provision which is "ultra vires" is null and void and therefore from the outset not applicable, i.e. irrespective of whether its content conflicts with the Article of the Convention concerned. Otherwise there would be no reason to deal with this issue as a separate point after point 57. Decisions J 11/91 and J 16/91 (OJ EPO 1994, 28, point 2.3.4 of the Reasons) of the Legal Board of Appeal, cited in the referring decision, contain a sentence stating that the Regulations may deal only with procedural questions and not with matters of substantive law. However, no reason is given in these decisions as to why this should be so. Furthermore, the said statement was only made in the context of discussing whether Rule 25(1) EPC 1973, as amended in 1988, was compatible with higher-ranking law, i.e. with Article 4G of the Paris Convention for the Protection of Industrial Property (the Paris Convention) and with Article 76 EPC 1973. This was denied. The Enlarged Board is not aware of any ground which would justify such a general assumption and the referring Board has also given none. It is the function of the Implementing Regulations to determine in more detail how the Articles should be applied and there is nothing in the Convention allowing the conclusion that this would not also apply in the case of Articles governing issues of substantive patent law. The limits to the Administrative Council's law-making powers by means of the Implementing Regulations can be inferred from Article 164(2) EPC. According to that Article, in case of conflict between the provisions of the Convention and those of the Implementing Regulations, the provisions of the Convention shall prevail. In decision G 2/93 (OJ EPO 1995, 275), the Enlarged Board of Appeal accepted that Rule 28 EPC 1973 implemented Article 83 EPC 1973 and was, at least in part, substantive in nature. Furthermore, in its more recent decision G 2/06 (OJ EPO 2009, 306, points 12 and 13 of the Reasons), too, the Enlarged Board did not doubt the Administrative Council's power to lay down provisions concerning substantive law in the Implementing Regulations.

2.3 Applicability of Rule 26(5) EPC to applications filed before the entry into force of Rule 23b(5) EPC 1973

Chapter VI of Part II of the Implementing Regulations to the EPC 1973, including Rule 23b(5) EPC 1973, now Rule 26(5) EPC, was incorporated into the EPC to take account of the provisions of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (the "Biotech Directive"). The new rules of Chapter VI entered into force on 1 September 1999. No transitional provisions were enacted. The application underlying appeal case T 83/05 was filed on 8 April 1999, thus before the entry into force of the new rules, and the referring decision has raised the question as to whether Rule 26(5) EPC (formerly Rule 23b(5) EPC 1973) can be applied to applications pending at the date of its entry into force. In the meantime, in decision G 2/06 (OJ EPO 2009, 306, point 13 of the Reasons) the Enlarged Board has answered a similar question relating to Rule 26(1) EPC (formerly 23b(1) EPC 1973) in a manner which settles the issue for the whole of Chapter VI (now V) of the Implementing Regulations and thereby also for Rule 26(5) EPC, namely: "The introduction of this new chapter without any transitional provisions, can only be taken as meaning that this detailed guidance on what was patentable and unpatentable was to be applied as a whole to all then pending applications.".

2.4 Question of Rule 26(5) EPC being in conflict with Article 53(b) EPC

Based on the assumptions that the approach to the interpretation of Article 53(b) EPC adopted by the boards of appeal prior to the introduction of Rule 23b(5) EPC

1973 reflected the true meaning of that Article, and that Rule 23b(5) EPC 1973 was aimed at a very narrow construction of Article 53(b) EPC 1973, and one which was hardly to be reconciled with the previous interpretation of that Article, the referring Board considers that Rule 23b(5) EPC 1973 is in conflict with Article 53(b) EPC 1973, contrary to Article 164(2) EPC. Reference is made by the referring Board to decision T 39/93 (OJ EPO 1997, 134, point 2.3 of the Reasons), in which it was held that, in view of Article 164(2) EPC, the meaning of an Article of the EPC on its true interpretation as established - in that case - by a ruling of the Enlarged Board of Appeal cannot be overturned by a newly drafted rule of the Implementing Regulations. As will be set out below, this reasoning is based on assumptions which are not endorsed by the Enlarged Board, so that a problem of conflict between Rule 26(5) EPC and Article 53(b) EPC in the sense described by the referring Board does not arise.

2.5 Protection of "legitimate expectations"

The same applies with respect to the further, related argument raised by the referring Board concerning the principle of protection of legitimate expectations. On the assumption that the introduction of Rule 23b(5) EPC 1973 changed the law by narrowing the scope of the process exclusion contained in Article 53(b) EPC 1973 and thus expanded the area of patentable subject-matter, it might be necessary to consider whether third parties should be protected in their expectation that an activity which amounted to an essentially biological process under the previous law could not be made the subject-matter of a patent resulting from an application filed before the entry into force of Rule 23b(5) EPC 1973. It was generally accepted by those involved in the proceedings before the Enlarged Board that any protection of "legitimate expectations" could only fall to be considered if the Enlarged Board's conclusion was that the introduction of Rule 23b(5) EPC 1973 changed the scope of the process exclusion contained in Article 53(b) EPC 1973, but not if the Enlarged Board solely deemed it necessary to make corrections to the approach in the jurisprudence hitherto, as established by decision T 320/87 (supra), which would not, however, be the result of the introduction of Rule 23b(5) EPC 1973. There can be no "legitimate expectation" that an interpretation of a substantive provision governing patentability given in a decision of the boards of appeal will not be overruled in the future by the Enlarged Board, since recognising such an expectation as legitimate would undermine the function of the Enlarged Board of Appeal. This holds particularly true for issues on which there is no solid body of decisions all to the same effect but where instead the relevant jurisprudence consists only of a very limited number of individual decisions, as is presently the case.

In the past, the Enlarged Board has granted a transitional period in cases in which the Enlarged Board's decision has brought about a change in relation to an established procedural practice which change the parties could not be expected to foresee. By contrast, for the reasons given above, the existence of "legitimate expectations" has never been acknowledged for issues before the Enlarged Board concerning the correct application, i.e. interpretation, of substantive patent law.

3. Article 53(b) EPC, "essentially biological processes for the production of plants"

The referred questions concern the interpretation of Article 53(b) EPC.

3.1 Text of Article 53(b) EPC

The provision reads:

"Article 53 Exceptions to patentability European patents shall not be granted in respect of:

(a) ...

(b) plant or animal varieties or essentially biological processes for the production of plant or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) ..."

3.2 Jurisprudence relating to Article 53(b) EPC 1973

3.2.1 T 320/87 and T 356/93

The standard definition of the term "essentially biological process" within the meaning of Article 53(b) EPC 1973 was developed in decision T 320/87 (supra, Headnote 1 and points 6 to 9 of the Reasons) and was confirmed in later decisions cited in the referring decision T 83/05, in particular decision T 356/93 (supra). In decision T 320/87 the Board held:

"6. ... whether or not a (non-microbiological) process is to be considered as "essentially biological" within the meaning of Article 53(b) EPC has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved. It is the opinion of the Board that the necessity for human intervention alone is not yet a sufficient criterion for its not being "essentially biological". Human interference may only mean that the process is not a "purely biological" process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of a quantitative or qualitative character.

7. ...

8. In analysing the claimed processes, it appears that their essence lies in the particular manner of the combination of specific steps ... The totality and the sequence of the specified operations do neither occur in nature nor correspond to the classical breeders' processes...

9. The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed. In some cases the effect of this can be seen in the result."

In decision T 356/93, cited by the referring Board in the present context, that Board undertook to explore more comprehensively the legislator's considerations when drafting the provision. After furthermore considering the findings in T 320/87 cited above, the Board then concluded that:

"28. ... 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 (see points 25 to 27 supra), does not fall under the exceptions to patentability under Article 53(b), first half-sentence, EPC."

3.2.2 G 1/98

In decision G 1/98 (OJ EPO 2000, 111), the Enlarged Board was already concerned with Article 53(b) EPC 1973, however, at that time in relation to the exclusion of plant varieties from patentability. The question raised by the referring Board in that case of how to decide whether a process can be defined as an "essentially biological process" was left unanswered. In its observations to the Enlarged Board of Appeal on the referring decision, the appellant stated that it had not been made aware of the referring Board's objections in that respect earlier than by the referring decision itself, but expressed its willingness to restrict the method claims to identifiable method steps in order to exclude essentially biological processes. In this situation, since the relevance to the application which had given rise to the referral of the question of how to decide whether a process can be defined as an essentially biological process had not yet been clarified by the referring Board, the Enlarged Board saw no need to reply to that question (loc. cit. point 6 of the Reasons).

Hence, although the said decision of the Enlarged Board explores in detail the legal history of Article 53(b) EPC in relation to the exception from patentability of plant varieties and to that extent also gives useful insights into the legislator's ideas at the time of drafting of the SPC and the EPC 1973 generally, its findings are not directly applicable to the interpretation of the exception of essentially biological processes from patentability.

3.2.3 Conclusions on jurisprudence relating to Article 53(b) EPC 1973

In the definitions given in that jurisprudence, in particular in decision T 320/87 (supra), the following elements can be identified as relevant to determining whether a process is not essentially biological:

1. The totality of human intervention and its impact on the result achieved is to be determined.
2. This has to be judged on the basis of the essence of the invention.
3. The impact must be decisive.
4. The contribution must go beyond a trivial level.
5. The totality and the sequence of the specified operations must neither occur in nature nor correspond to the classical breeders' processes.
6. The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed.

In some cases the effect of this can be seen in the result. It is not entirely clear from decision T 320/87 which of the defined elements were thought to be the decisive ones and which were potentially only secondary considerations, but it is to be noted that the later decision T 356/93 focuses on the presence of a technical step which cannot be carried out without human intervention and which has a decisive impact on the final result (3.2.1 supra).

3.3 Impact of jurisprudence relating to Article 53(b) EPC

The clause in Article 53(b) EPC 1973 concerning the exclusion of essentially biological processes from patentability was not reconsidered when the EPC 2000 was drafted and Article 53(b) EPC remained unamended in this respect. Therefore, the jurisprudence described in the foregoing has not become inapplicable merely as a result of the revision of the EPC.

4. Rule 26(5) EPC

However, an important addition to the legal texts to be considered in the matter was created by the introduction of the then Rule 23b(5) EPC 1973 into the Implementing Regulations. Apart from being renumbered as Rule 26(5), the text of Rule 23b(5) EPC 1973 remained untouched in the revision of the Implementing Regulations to the EPC 2000. Rule 26(5) EPC reads:

"(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

According to Rule 26(1), first sentence, EPC, for European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of Chapter V (formerly VI) "Biotechnological inventions", to which Rule 26 EPC belongs.

4.1 Relationship of the Rule to Article 2(2) Biotech Directive

Furthermore, Rule 26(1), second sentence, EPC (formerly Rule 23b(1), first sentence, EPC 1973) stipulates that the Biotech Directive shall be used as a supplementary means of interpretation. The wording of Rule 26(5) EPC is identical to Article 2(2) Biotech Directive.

4.2 Do the provisions give an exhaustive definition?

The argument was advanced that Rule 26(5) EPC was not meant as a(n exhaustive) definition of when a process is essentially biological within the meaning of Article 53(b) EPC but was only meant to serve as a reference, i.e. as an illustrative example of one of the kind of cases covered by the exclusion.

However, Recital 33 of the Biotech Directive reads: "Whereas it is necessary to define (emphasis added by the Enlarged Board) for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological".

Furthermore, the Statement of Council's Reasons for the Common Position of 26 February 1998 (OJ EC C 110, 8.4.1998, p.27, no. 12 and 13) refers to Article 2(2) Biotech Directive as being a complete definition.

Hence, Rule 26(5) EPC can, in accordance with the Biotech Directive, only be interpreted as being meant to give an exhaustive definition.

4.3 Principles of interpretation

Both legal texts must be interpreted following the principles of interpretation enshrined in the Vienna

Convention on the Law of Treaties of 23 May 1969 ("Vienna Convention"). According to Article 31(1) of the Vienna Convention, "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."
Furthermore, Article 32 Vienna Convention stipulates that "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable."

4.4 Meaning of the terms "crossing" and "selection"

It was argued in the proceedings that crossing and selection should be understood to mean only crossing and selection as they take place in nature. In particular, the term selection did not address the selection made by man in a breeding process but only the selection that takes place in nature and is not controllable by man, and that determines which plants survive in nature, depending also on the particular environmental conditions involved. Pursuant to Article 31(1) Vienna Convention, the meaning of a term of a treaty cannot be established in a purely semantic manner but its interpretation must be made in good faith, in accordance with the ordinary meaning to be given to the terms of the treaty in their context. Considered from this angle, a definition which completely disregards the fact that the context of the terms crossing and selection in the said provisions is given by the processes for the production of plants (German version: "Züchtung von Pflanzen", French version "obtention de végétaux"), i.e. the breeders' activity, cannot be the right one. In that context the terms "crossing" and "selection" refer to acts performed by the breeder. These are characterised by the fact that the breeder intervenes in the processes in order to achieve a desired result. Hence, in that context, crossing and selection are not natural phenomena but are method steps which generally involve human intervention. In decision T 1242/06, point 10. of the Reasons, the referring Board rightly remarked that to find that the terms "crossing" and "selection" in Rule 26(5) EPC are intended not to refer to plant breeding at all but only to purely natural events taking place without human control would have the awkward consequence of restricting the scope of the exclusion to subject-matter which, owing to its complete lack of technical character, would not qualify as an invention anyway, so that there would be no need to exclude it from patentability by an explicit provision.

4.5 "Crossing" and "selection", natural phenomena by way of a legal fiction?

Admittedly, this result does not make the interpretation of Rule 26(5) EPC easier, since on the one hand (only) processes which consist entirely of natural phenomena are considered to be essentially biological processes for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena, but the systematic crossing and selection carried out in plant breeding are not natural phenomena but measures implemented by means of human intervention. Hence, the wording of Rule 26(5) EPC is ambiguous, if not contradictory. This does not, however, justify the conclusion that the ambit of Rule 26(5) EPC is to define crossing and selection as natural phenomena by way of a legal fiction. There is nothing in the text of the provision as it stands today that would justify such a conclusion. In terms of legal methodology, the fact that crossing and selection are mentioned only as examples ("such as") of natural phenomena speaks against reading Rule 26(5) EPC as a legal fiction in the sense that crossing and selection should thereby be defined as natural phenomena in the legal sense even if they are not. With the exception of some editorial considerations which had to be dealt with, in the interest of uniformity in harmonised European patent law, the provisions of the Biotech Directive, which were not yet contained in the Convention and related to substantive patentability requirements, were incorporated into the Implementing Regulations as they stood, see the Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention (OJ EPO 1999, 573, point 19, explanatory notes to Rule 23b(5)), which simply states that the interpretation developed by the boards falls within the framework of the definition given in the new rule. Hence, it is the text of the Biotech Directive and its legal history which have to be considered when looking for further clarification of the meaning to be given to Rule 26(5) EPC.

4.6 Object and purpose of the definition according to the Biotech Directive

The recitals of the Biotech Directive contain nothing on the object and purpose of the definition given, other than saying in Recital 33 that it is necessary to define for the purpose of the Directive when a process for the breeding of plants and animals is essentially biological.

4.7 Legislative history of Article 2(2) Biotech Directive

It is therefore necessary to look more closely at the legislative history of the Biotech Directive, in particular how the final version of Article 2(2) Biotech Directive was arrived at, including the main changes that were made to the texts in the course of the drafting work.
4.7.1 Article 7 of the (first) Proposal for a Council Directive on the legal protection of biotechnological inventions submitted by the Commission on 20 October 1988 (COM(88) 496 final - SYN 159, 13.1 1989, OJ C 10, p. 3) - the first version reported in point 51 of the Reasons of decision T 83/05 - read:
"A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter".
Additionally, recital 17 provided that:
"Whereas it is necessary to encourage potential innovation in the full range of human endeavours by recognizing that human intervention which consists of

more than the selection of biological material and allowing such material to perform inherently biological functions under natural conditions should be considered patentable subject-matter and should not be regarded essentially biological".
In the explanatory memorandum of the Commission to the proposal (COM(88) 496 final - SYN 159 - of 16 October 1988, Part II, Chapter 1, Article 3, p. 33, Article 5, p. 38, and Article 7, p. 40 to 41), the Commission takes the view that by contrast to the then EPO Examination Guidelines, which required that human intervention must play a "significant part" in determining or controlling the result it is desired to achieve, Article 7 of the Biotech Directive is intended to exclude only traditional biological breeding activities based upon selection and as such may be regarded as slightly more liberal than the Guidelines, with the consequence that any human intervention aside from selection, such as influencing the crossing procedure or the replication process, would remove the process from the field of "essentially biological" processes. According to the Commission, this is justified because the exceptions to patentability for the categories of inventions relating to plant and animal varieties and essentially biological processes for producing plants and animals were created under certain conventions on the basis that these inventions lacked industrial applicability. But the distinction between "essentially biological" and "not essentially biological" processes has become artificial as a consequence of biotechnological techniques having effectively rendered this difference of little practical value.
4.7.2 Such a narrow approach to the exception from patentability was not accepted by the European Parliament, which in October 1992 approved the text with (inter alia) an amended text of the then Article 7 (OJ C 305, 23.11.1992, p. 161, amendment n° 25), Recital 17 remaining unamended: "Essentially biological procedures shall not be patentable. Whether or not a procedure is to be so classified shall be determined on the basis of the nature of the invention, having regard to the extent of human intervention and its impact on the result achieved." This is an almost verbatim citation of Headnote 1 of decision T 320/87 (supra).
4.7.3 On 16 December 1992 the Commission put forward an amended proposal which took into account the amendments of the European Parliament (Com (92) 589 final - SYN 159). In the Common Position (EC) No 4/94 adopted by the Council on 7 February 1994 (OJ C 101 9.4.1994, p. 65) - the second version mentioned in T 83/05 - Article 6 stated:
"In determining this exclusion, human intervention and its effects on the result obtained shall be taken into account. A process which, taken as a whole, does not exist in nature and is more than a traditional breeding process shall be considered patentable".
Recital 27 stated:
"(27) whereas it is necessary to encourage potential innovation in the full range of human endeavours by recognizing that human intervention and its impact on the result achieved must be taken into account in determining whether the exclusion from patentability of essentially biological processes applies, it being understood that a process which, taken as a whole, does not exist in nature and is more than a mere traditional breeding process is patentable".
This version differed only slightly from the amended proposal of the Commission.
In both versions, the first sentence takes account of the broader meaning given to the exclusion by the European Parliament. However, the second sentence of each version maintains, as to the substance, the narrower interpretation originally proposed by the Commission, with the amendments now made to the original version concerning more matters of wording than of substance.
4.7.4 The text of that (first) Common Position was integrally rejected by the European Parliament on 25 January 1996 (OJ C 068, 20.03.1995, p. 26).
4.7.5 Thereafter, the Commission submitted a new proposal (OJ C 296, 8.10.1996, p. 4).
Article 2, no.3 of that proposal read:
"3. Essentially biological process for the production of plants or animals means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal-breeding process."
Recital 18 of the proposal considered:
"(18) Whereas, for the purposes of determining whether or not it is possible to patent essentially biological processes for obtaining plants or animals, human intervention and the effects of that intervention on the result obtained must be taken into account;..." In this version the wording representing the narrower approach to the exclusion remained in the Article, whereas the broader version was shifted to the Recital.
4.7.6 This proposal was debated by the European Parliament. The European Parliament delivered its Opinion on first reading on 16 July 1997 (OJ C 286, 22.09.1997, p.87) and voted inter alia for the following amendments:
(Amendment 48)
Article 2
....
"3b. A procedure for the breeding of plants or animals shall be defined as essentially biological if it is based on crossing or selection."
(Amendment 22)
Recital 18:
"(18) Whereas a procedure for the breeding of plants and animals is essentially biological if it is based on crossing whole genomes (with subsequent selection and perhaps further crossing of whole genomes);..."
It is immediately apparent that this version of the texts reflects a broader understanding of the exclusion and would, at least arguably, have excluded from patentability all processes based on crossing and selection, irrespective of the degree or kind of human intervention needed in order to bring about the desired result.
4.7.7 In its amended proposal of 29 August 1997 for a European Parliament and Council Directive on the legal protection of biotechnological inventions (OJ C 311, 11.10.1997, p.12 - the third version reported in T

83/05), the Commission incorporated the aforecited amendments voted for by the European Parliament.
4.7.8 These amendments were, however, eventually not taken over as such by the Council, which drafted the wording of Article 2(2) Biotech Directive and Recital 33 (instead of Recital 18) in its (second) Common Position (EC) No 19/98 adopted on 26 February 1998 (OJ C 110, 8.4.1998, p.17) as follows and as these texts stand today:
"Article 2
...
2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."
Recital 33
"(33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological;..."
In points 12 and 13 of the Statement of the Council's Reasons pertaining thereto it is said:
"12. The Commission incorporated paragraph 3b of the European Parliament's amendment 48 in paragraph 2 of its amended proposal. The Council tightened up the definition of the essentially biological notion of procedure in this provision on the basis not only of amendment 48 but also of amendment 22 proposed by the European Parliament with regard to recital 18 of the original proposal.
13. Given the inclusion of a complete definition in Article 2(2), the Council made the corresponding recital declaratory in tone (recital 33 of the common position)."
4.7.9 The Common Position was communicated by the Commission to the European Parliament on 4 March 1998, by document SEC(1998)360 final. In that document, point 3.2, "Amendments adopted by Parliament at first reading", reads: "The amendments accepted by the Commission and incorporated into its amended proposal have also been incorporated into the common position.
They are as follows:
...
Amendment 22 Recital 33
...
Amendment 48 Articles 2 and 3"
Point 3.3, "Amendments tabled during the Council discussion", reads with respect to Recital 33: "Parliament's amendment 22 defined with some technical precision the concept of an essentially biological procedure for the breeding of plants and animals. To avoid any problems of interference between Article 2(2) of the draft Directive, which defines this idea, and Recital 33, the Council thought it preferable that the technical aspects of the concept should be incorporated into Article 2(2). As a result, Recital 33 now reads like a statement of the issue."
With respect to Article 2 the document reads: "The Council thought it more appropriate that Article 2(2) should incorporate all the technical aspects of the definition of an essentially biological process for the production of plants or animals (see remarks on Recital 33)."
4.7.10 The European Parliament subsequently approved the Directive by decision of 12 May 1998 (OJ C 167, 1.6. 1998, 26).

4.8 Conclusions on 4.7

4.8.1 From a comparison of the different draft versions and the final text of Article 2(2) Biotech Directive it becomes apparent how - mainly as a consequence of the consecutive amendments voted for by the European Parliament - the terms of the definitions in the earlier versions gradually shifted from a very narrow to an at least partially broader construction of the exclusion. The first version (4.7.1 above) defines as patentable a process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions. The second and a further version (4.7.3 and 4.7.5 above) basically still retain the substance of that narrow construction by referring to a "process which, taken as a whole, does or does not exist in nature" and to whether it is more than a "traditional breeding process" or a "natural plant breeding process". However, from the second version on, the text also comprised the definition voted for by the European Parliament that, in determining the exclusion, human intervention and its effects on the result obtained shall be taken into account. This part of the draft definitions was basically in accordance with the principles developed by the boards of appeal, in particular in decision T 320/87 (supra). This was in line with the general ambit of the Biotech Directive, which was not to set up a new system of protection for biotechnological inventions, but to provide for effective, clear and harmonised protection in that field, see in particular Recitals 3 and 8 Biotech Directive, but also the Commission's Explanatory memorandum to its (first) Proposal for a Council Directive (COM(88) 496 final - SYN 159, point 8, and the reference to the EPC in point 14). With regard to substantive requirements of patentability for which there was already an EPO practice, protection for biotechnological inventions was essentially achieved by adopting the concepts developed under the EPC (see e.g. the definitions of the following: "biological material" in Article 2, 1.(a) and Recital 15; "discovery" vs. "invention" in Article 3, 2. and Recitals 13,16 and in particular 34; "patentable inventions concerning plants in relation to plant varieties" in Article 4(2) and Recitals 9 and 29 to 32 (based on the Office's approach, not on decision T 356/93, which was later overruled by the Enlarged Board's decision G 1/98) and concerning "elements isolated from the human body" in Article 5(2) and Recitals 16,17 and in particular 20 to 24).
4.8.2 Matters then changed, however, as a result of the amendments to the then Article 3b and Recital 18, reported under 4.7.6 above, voted for by the European Parliament. By defining a "procedure for the breeding of plants" as essentially biological if it is based on crossing (whole genomes, according to Recital 18) or (sic) selection, and thereby, at least arguably, excluding

from patentability (all) processes based on crossing and selection, irrespective of the degree of human intervention in the process and of its impact on the result, the European Parliament gave the exclusion a broader meaning.

4.8.3 The Council's comments in the statement of reasons for the Common Position about "tightening up" the definition and the Commission's remarks, when it submitted the Common Position to the Parliament, that the "technical aspects of the concept (of essentially biological, addition by the Enlarged Board) should be incorporated into Article 2(2)" (instead of in Recital 33, addition by the Enlarged Board) might suggest that the amendments made by the Council to the text voted for by the Parliament were only a matter of legislative technique and not intended to deviate from the substance of the formulation as voted for by the Parliament. However, apart from the fact that the term "tightened up" is anything but unambiguous, and that the point of referring to terms of a legal definition as "technical aspects" is difficult to understand, it must be stated that, if it was the intention of the Council to preserve the substance of the amendments voted for by the European Parliament and only to express this substance in different words, this aim was not achieved. Even though the wording of the texts as finally enacted by the Council is unclear and contradictory, it is nonetheless evident that the objective meaning of the definition given in Article 2(2) Biotech Directive corresponds neither to the amendments voted for by the European Parliament nor to the substance of the earlier drafts, but rather is definitely something different. While the first part of the definition, with its reference to processes consisting entirely of natural phenomena, might at first sight appear to take up the substance of earlier drafts comparing the claimed processes with processes which, as a whole, exist in nature, and which occur under natural conditions, the second part of the definition, which refers to crossing and selection, appears to take up the Parliament's definition according to which processes based on crossing (whole genomes) and selection should be excluded from patentability as being essentially biological. The effect of combining the two elements of different concepts into a single definition and citing one of these concepts as an example of the other was to reinforce the contradiction in meaning of the provision, as compared to the earlier drafts mentioned above. It is also worth noting that the earlier draft concepts referring to processes as they exist in nature nowhere express the notion that crossing and selection as such are natural phenomena or should be regarded as such. They only say that a process which, taken as a whole, exists in nature or is no more than a natural plant-breeding process is essentially biological.

As a result, the legislative history of the Biotech Directive does not assist in determining what the legislator intended to say by the wording which was eventually adopted for Article 2(2) Biotech Directive. On the contrary, it must be concluded that the contradiction between the terms of the provision cannot be further clarified.

5. Conclusions on the impact of Rule 26(5) EPC on the interpretation of Article 53(b) EPC. As a consequence of Rule 26(5) EPC not having a legal history of its own, the foregoing also applies to that Rule. As has been set out under 2.2 above, the legislator is entitled to provide for issues of substantive law in the Rules of the Implementing Regulations. However, in order to enable the Article to which a Rule pertains to be interpreted by means of the Rule, such Rule must at least be clear enough to indicate to those applying it in what way the legislator intended the Article to be interpreted by means of that Rule. This is not the case for Rule 26(5) EPC. It is notable, furthermore, that, as is to be derived from document CA/PL/ 3/99, point 23, the legislator of the EPC did not intend to overrule any jurisprudence of the boards of appeal. On the contrary, the document states that: "Although the EPO boards of appeal have hitherto not given an explicit decision to that effect (see T 320/87, T 19/90, T 356/93), the interpretation developed by the boards falls within the framework of the proposed definition". Be it as it may, the consequence of the self-contradictory wording of Article 2(2) Biotech Directive having been transposed verbatim into Rule 26(5) EPC is, regrettably, that Rule 26(5) EPC does not give any useful guidance on how to interpret the term "essentially biological process for the production of plants" in Article 53(b) EPC and therefore that term must be interpreted on its own authority. This is for the Enlarged Board to do.

6. Interpretation of the exclusion of "essentially biological processes for the production of plants" in Article 53(b) EPC

6.1 The meaning of the wording of the terms

6.1.1 Plant vs. plant variety

It was argued in the proceedings that since the purpose of excluding essentially biological processes for the production of plants from patentability was only to give full effect to the ban on dual protection under the International Convention for the Protection of New Varieties of Plants (UPOV Convention), the term "plant" should be read as meaning that the exclusion was limited to processes for the production of plant varieties. The importance of the difference between the terms "plant" on the one hand and "plant variety" on the other hand was examined in the Enlarged Board's decision G 1/98 (supra). In that decision the Enlarged Board held in point 3.1 of the Reasons (loc. cit., p. 125 to 126) with reference to the definition in Article 1(vi) of the UPOV Convention 1991, that "the term (plant) "variety" means a plant grouping within a single botanical taxon of the lowest rank, which grouping, ..., can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, ... In contrast, a plant ... is an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genome or by a property bestowed on it by that part". More importantly, according to point

3.3.1 of the Reasons, the difference in wording within the same halfsentence of the provision referring to "plant" on the one hand and "plant variety" on the other

hand must be supposed to have some meaning. With respect to the term "plant variety", the provision would use the more general term "plants" as used for the processes if it was the intention to exclude plants as a group embracing in general varieties as products. The converse also holds true when it comes to determining the meaning of the excluded processes for the production of plants vs. the excluded protection for plant varieties.

In the drafting process for the EPC 1973, the then Article 12 of the first Preliminary Draft Convention of the EC working group of 14 March 1961 (Doc IV 2071/61-E) already provided in its paragraph 2 for an exception from patentability of a "process for producing a new plant "variety" ...". This wording was amended in the course of the drafting work to read "processes for the production of plants", which became the final version of the provision. Furthermore, as is reported in detail in points 40 and 41 of the Reasons of referring decision T 83/05, at that point in time the preliminary drafts of the EPC contained the exceptions from patentability of "new plant or animal species or of purely biological, horticultural or agricultural (agronomic) processes", which formulation was also later amended to the current wording as contained in the SPC and the EPC. Admittedly, the comments reproduced in point 38 et seq. of the Reasons of referring decision T 83/05 show a certain interchange between the use of the terms "plant", "plant species" and "plant variety". Furthermore, no real explanation can be derived from the preparatory documents as to why the initial terms "plant variety" or "plant species" were eventually replaced by the term "plants". However, in the absence of any indication in the legislative history that the term "plants" was meant to signify only "plant varieties", and in view of the importance of the difference in legal meaning of the term "plant" on the one hand and "plant variety" on the other, as demonstrated by the Enlarged Board's decision G 1/98, any interpretation of the term "plant" as meaning, contrary to its wording, only "plant varieties", is ruled out. Hence, the Enlarged Board concludes that the exception of "essentially biological processes for the production of plants" cannot be read as only applying where the result of such a process is a plant variety. In other words, it cannot be read as being limited to processes for the production of plant varieties.

6.1.2 Production vs. "Züchtung" and "obtention"

It was also argued in the proceedings that the term "production" was much broader in its meaning than the terms "Züchtung" and "obtention" used in the other two official languages, and the Enlarged Board was asked to clarify the meaning of that term. Both cases as they underlie the referring decisions are concerned with processes in which the desired trait of the plant is achieved by crossing and selection, i.e. they are breeding methods. Hence, any potential difference in the meaning of the English wording of Article 53(b) EPC "method for the production" as compared with its German and French texts ("Züchtungsverfahren", "procédé d'obtention") does not appear relevant for the presently referred issues.

6.1.3 Essentially biological

Any attempt to determine a reliable literal meaning for the term "essentially biological" process appears futile. Under the EPC, the legal situation today is that jurisprudence has existed for many years - for the cases underlying the referring decisions, this is above all decision T 320/87 (supra) - that has set a standard for the interpretation of the exclusionary clause. Hence, what the Enlarged Board must now consider is whether the approach as adopted in decision T 320/87 holds good. In referring decision T 83/05 (point 46 of the Reasons), the Board, making reference to its own prior referring decision T 1054/96 (OJ EPO 1998, 511, Referral G 1/98), identifies two further possible approaches to the exclusion of essentially biological processes for the production of plants and animals from patentability.

6.2 The Article 52(4) EPC 1973 analogy

The first approach would be analogous to that used under Article 52(4) EPC 1973 in relation to methods of treatment by surgery and therapy and would result in the inclusion in a claimed process of a step of an essentially biological nature not being allowable. However, it already follows from the wording of the exclusion, which requires the claimed process, i.e. the process as a whole, to have a biological "essence" (whatever that may mean precisely), that the mere presence of one biological feature in a process cannot automatically confer an essentially biological character on the process as a whole.

6.3 The computer-related inventions approach

The same applies to the converse approach. That second approach would be to require, in order for the process to escape the prohibition of Article 53(b) EPC, at least one clearly identified "non-biological" process step, while allowing any number of additional "essentially biological steps", which would be carried into allowability by the "non-biological" process step. In the present proceedings the argument was also based on the proposal that an analogy should be drawn with the principles developed for determining the technical character of certain computer-implemented inventions. Following the abandonment of the "contribution approach", it was established in decision T 258/03 (OJ EPO 2004, 575, Headnote 1 and points 4.3 et seq. of the Reasons) that any method claim involving technical means is not excluded from patentability by Article 52(2) EPC (see also the Enlarged Board's opinion G 3/08 of 12 May 2010, to be published, point 10.7 of the Reasons). It can, however, already be concluded from the difference in the wording of Article 52(2) EPC from that of Article 53(b) EPC that the suggested comparison does not hold good. According to Article 52(3) EPC, paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such. This is interpreted in the jurisprudence as meaning that "any technical means" makes the claimed subject-matter escape the exclusion under Article 52(2)

EPC (see G 3/08, loc. cit.). By contrast, for the exclusion under Article 53(b) EPC to apply, it suffices that the claimed process be essentially biological. However narrowly one might wish to construe the reference to some kind of "essentiality", any possibility of interpreting the exclusion in the sense that any technical feature, irrespective of its importance for an otherwise biological process for the production of plants, makes the process escape the exclusion under Article 53(b) EPC, is thereby also ruled out from the outset.

6.4 The T 320/87 approach

6.4.1 Criteria linked to the state of the art

In decision T 320/87 (supra) several criteria were used for assessing whether the claimed invention is essentially biological or not (see 3.2.1 above). Some of these are defined in such a way that determining whether they are fulfilled depends on the state of the art to be taken into account in the individual case. This applies to the questions whether the totality and sequence of the specified operations do or do not correspond to the classical breeders' processes, whether they occur in nature or whether a technical feature in the claim is trivial or alters the character of a known process in a fundamental way or whether the essence of the claimed invention lies in it, to the extent that the essence of the invention is determined on the basis of the objective problem solved. Basically, any approach that makes the decision on whether a claimed process for the production of plants is essentially biological and therefore excluded from patentability, or technical and therefore patentable, dependent on criteria which are determined by reference to the state of art is flawed because it conflates the considerations which are relevant for patentability with those relevant for novelty and inventive step. Furthermore, such an approach is detrimental to legal certainty, since the qualification of a process as being patentable subject-matter or, on the contrary, excluded from patentability could then change with every new state of the art that comes to be considered in the various procedural stages which an application and a patent granted on it may run through during the whole lifetime of the patent. There is, furthermore, simply no logic in saying that the decision whether a process is technical or essentially biological depends on what was already known or used in the art or on how far the claimed subject-matter went beyond that. In the area of delimiting unpatentable non-technical subject-matter under Article 52(2) EPC from technical inventions, it has long been recognised that "it may be determined whether a claim to a computer program is excluded from patentability by Articles 52(2) and (3) EPC independent of the prior art" (T 1173/97, OJ EPO 1999, 609, point 13 of the Reasons; G 3/08, point 10.4 of the Reasons; see also T 258/03, loc. cit., points 4.3 and 4.4 of the Reasons). The same should apply to the delimitation of unpatentable essentially biological from patentable technical subject-matter. Hence, it cannot be decisive whether a technical measure is known or trivial or what methods are already used by plant breeders. Otherwise, the very same operation, such as the one characterised in decision T 320/87 (supra) as not essentially biological, would turn into an essentially biological one, once it has become known and found entrance into plant breeders' sets of routine operations. As is already apparent from the historical documentation to the EPC/SPC (which mentions special grafts or greenhouses or irradiation of seeds to induce mutagenesis), plant breeders have always made use of technical means which help to bring about the desired breeding result, and a plant breeder will normally wish to profit from the most efficient technologies available to him. Hence, what is new today may be conventional tomorrow. Modern but nevertheless already "classical" plant breeding technologies make wide use of advanced technical methods in the context of the steps of crossing, growing and selection. Often the use of a technical means is only implicit in the definition of a crossing or selection step in the claim, such as with the weighing and drying in the context of selecting plants with tomato fruits having an increased dry weight percentage, as required by claim 1 of auxiliary request I in the case underlying referring decision T 1242/06. Technical means used today are often steps performed in the laboratory, such as the use of molecular markers to facilitate the selection for the desired properties, as in the case underlying referring decision T 83/05. It is thus clear that the characterisation of a breeding process as a "classical" breeding process as such tells nothing about whether this process is essentially biological or whether it has a technical character. It is not because steps taken in a breeding process are known that they can no longer serve to confer a technical character on the process. Conversely, even the use of a new technical measure cannot as such confer a technical character on an otherwise biological process. The same considerations apply to the criterion of whether the essence of the claimed invention lies in the technical feature, to the extent that the essence of the invention is determined on the basis of the objective problem solved. This is because the objective problem solved may have to be redefined when a new state of the art falls to be considered in the procedural stage reached. Hence, it must be deduced from the use of the term "essentially" that, in contrast to the position when determining the technical character of an invention in relation to Article 52(2) EPC, not just "any" technical means will suffice to make a claimed invention escape the exclusion under Article 53(b) EPC (see above under 6.3). On the other hand, it does not follow from the law excluding "essentially" biological processes that the inventive essence of the process is to be determined by applying the same criteria as used for determining the presence of an inventive step. Summarising, it follows that criteria which link the decision on whether a process for the production of plants is essentially biological or technical to what is known or used in the prior art are not the right ones. In its decision "Tetraploide Kamille" the Tribunal of Commerce of the Canton of Bern ("Handelsgericht des Kantons Bern") decided in the same way (GRUR Int. 1995, 511, 517).

6.4.2 Human intervention

In decision T 320/87 (supra) the Board held that a further criterion for delimiting unpatentable essentially biological processes from patentable processes was the totality of human intervention in the process and its impact on the result achieved. In decision T 356/93 the Board concluded 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), first half-sentence, EPC" (point 28 of the Reasons, for further details see 3.2.1 and 3.2.3 above).

6.4.2.1 The systematic context and objective purpose of the exclusion in Article 53(b) EPC

The exclusion of essentially biological processes for the production of plants from patentability has and always has had its place in a provision which defines exceptions from patentability. It is common ground that, by contrast to the subject-matters listed in Article 52(2) EPC, the subject-matters listed in Article 53 EPC are inventions but shall, however, not be patentable. That this is the idea underlying Article 53 EPC was clearly reconfirmed by the legislator when revising the EPC 1973. When the EPC 2000 was established, Article 52(4) EPC 1973 was transferred to Article 53 EPC as its new letter (c). The following reasons were indicated for this change:

"The exclusion of methods of treatment and diagnostic methods referred to in Article 52(4) EPC 1973 has been added to the two exceptions to patentability in Article 53(a) and (b) EPC. While these surgical or therapeutic methods constitute inventions, ... It is therefore preferable to include these inventions in the exceptions to patentability in order to group the three categories of exceptions to patentability together in Article 53(a), (b) and (c) EPC." (Revision of the European Patent Convention (EPC 2000) Synoptic presentation EPC 1973/2000 - Part I: The Articles, Special edition OJ EPO 4/2007, p. 50). Human intervention, to bring about a result by utilising the forces of nature, pertains to the core of what an invention is understood to be. Like national laws, the EPC does not define the term "invention", but the definition that was given many years ago in the "Red Dove" ("Rote Taube") decision of the German Federal Court of Justice ("Bundesgerichtshof"), BGH 27.3.1069, X ZB 15/67 set a standard which still holds good today and can be said to be in conformity with the concept of "invention" within the meaning of the EPC. In that decision, in the version of the translation into English published in 1 IIC (1970), 136, the German Federal Court of Justice defined the term "invention" as requiring a technical teaching. The term technical teaching was characterised as "a teaching to methodically utilize controllable natural forces to achieve a causal, perceivable result" (point 3 of the Reasons). In its German original (GRUR 1969, 672, point 3 of the Reasons), that passage reads: "eine ... Lehre zum planmäβigen Handeln unter Einsatz beherrschbarer Naturkräfte zur Erreichung eines kausal übersehbaren Erfolges". The term "technology" (in German "Technik"), which is now enshrined in Article 52(1) EPC but which at all material times underlay the understanding of the term "invention", was deliberately not defined by the legislator in order not to preclude that adequate protection would be available for the results of developments in the future in fields of research which the legislator could not foresee (see also "Red Dove", loc. cit. point 1 of the Reasons). Ever since then, biological forces and phenomena, to the extent that they are controllable, have been considered to pertain to the area of technologies in which patentable inventions are possible (for examples and details, see "Red Dove", loc. cit. point 4 of the Reasons). For biotechnological inventions this is now explicitly enshrined in the EPC and in the Biotech Directive. Biotechnological inventions are inventions relating to biological material, Rule 26(2) EPC. Plants are biological material within the meaning of Rule 26(3) EPC. Plants and their parts are a material substrate which can be processed by man to achieve a desired result by using natural forces, i.e. by systematically using the biological mechanisms underlying the process steps suggested in the claim. The enormous progress in knowledge in this field has brought about processes which can be controlled by man in a manner sufficient to make them reproducible. As the essentially biological processes for the production of plants are excluded from patentability by Article 53(b) EPC even though they are inventions and are as such characterised by human intervention, the Board in T 320/87 (supra) was fundamentally correct in its starting point that not just any kind of human intervention can suffice to make an invention in this field escape the exclusion. In order to determine more precisely how the excluded kinds of processes involving human intervention are properly to be delimited from the patentable ones, it is necessary to consider the purpose of the exclusion. However, since the respective legislative purposes behind the sub-items in Article 53 EPC and even those behind the alternatives of Article 53(b) EPC are quite different, the systematic context of the exclusion of essentially biological processes from patentability, namely its place in Article 53(b) EPC, does not as such indicate what the purpose of the provision is. It only allows the conclusion that some kinds of processes must be excluded even though they are inventions, and that, hence, the exclusion may not be interpreted in such a way that it would be entirely deprived of any field of application and thereby rendered obsolete.

6.4.2.2 The object and purpose of the exclusion as derivable from the legislative history of the SPC and the EPC 1973

In the EPC revision Article 53(b) remained untouched. It is therefore necessary to go back to the EPC 1973, viz the SPC, on which the EPC was modelled. Against the background of the draft of the UPOV Convention (finally concluded on 2 December 1961) and the so-called ban on dual protection contained in it, Article 12 of the first Preliminary Draft Convention of the EC Working Group of 14 March 1961 (Doc IV 2071/61-E) already provided in its paragraph 2 for an exception from patentability for "inventions relating to the pro-

duction of or a process for producing a new plant variety or a new animal species". Paragraph 2 furthermore provided that this provision shall not apply to processes of a technical nature. The explanations given in the comments on the Draft Convention specify that even if protection of new plant varieties and processes for producing new plants (sic) are excluded, patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g. processes for producing new plants by irradiation of the plants themselves or the seeds with isotopes (see the texts reproduced in point 39 of the Reasons of T 83/05). In the Preliminary Draft (SPC) Convention of the Council of Europe the (optional) exception from patentability in respect of new plant or animal species (sic) was contained in Article 2, which dealt with "Industrial Character" and generally provided that the words "susceptible of industrial application" shall be understood in the widest sense. In a meeting of the Committee of Experts of the Council of Europe subsequent to the aforementioned meeting of the EC working group, the words "or purely biological, horticultural or agricultural (agronomic) processes" were added to the (optional) exclusion of new plant or animal species from patentability in draft Article 2 SPC, without any further specification of the kind of excluded processes (EXP/Brev (61) 2 rev., p. 10, 11 and 26, T 83/05, point 40 of the Reasons). These were thus not limited to processes for the production of plants or animals. It can be deduced from the discussion reported in that document (EXP/Brev (61) 2 rev., p. 10, point 16) and from the later document EXP/Brev (61) 8, p. 4, point 6, that the exclusion of horticultural or agricultural processes was foreseen because some national laws excluded these areas from patentability and Article 2 was to leave the states concerned free to exclude certain classes of biological inventions from patentability. By contrast, no explanation is apparent as to why the "purely biological" processes were also mentioned in this exclusion clause.

Thereafter representations were made that, in the interest of a more efficient unification of the laws, the paragraph containing the abovementioned exceptions, including the reference to plant or animal species, should be deleted altogether. At least, however, the reference to the "purely biological, horticultural or agricultural processes" should be deleted (Statement presented by the Danish, Norwegian and Swedish experts, EXP/Brev (61) 5, on page 3 also making reference to a corresponding AIPPI resolution). After discussions in a committee meeting of 7-10 November 1961, the reference to "horticultural or agricultural (agronomic)" was deleted from Article 2 and shifted to Article 6, thereby allowing the contracting states only to make a temporary reservation. As regards the biological processes, the remaining phrase "purely biological processes" was replaced by the current wording "essentially biological processes for the production of plants and animals" (EXP/Brev 61(8), p. 4-5). Thereby the text of the exclusion clause as it still stands today in the EPC was laid down. The reasons given for this amendment therefore appear of particular importance. Reference is made to point 40 of the Reasons of referring decision T 83/05, in which the explanations are reproduced verbatim. According to the explanations given, the (essentially biological) processes for the production of plants or animals should include those which may produce known varieties as well as those which may produce new ones. Selection or hybridization of existing varieties are mentioned as examples of such processes. The replacement of "purely" by "essentially" is expla ined by the reasoning that it was evident that the exclusion should be extended to cover processes which were fundamentally of this type, even if, as a secondary feature, "technical" devices were involved (use of a particular type of instrument in a grafting process, or of a special greenhouse for growing a plant), it being understood that while such technical devices may perfectly well be patented themselves the biological process in which they are used may not. As the referring decision T 83/05 sets out in points 40 and 41 of the Reasons, these explanations were repeated almost verbatim in a later report of the Committee of Experts to the committee of ministers, and the wording on which the Committee of Experts of the Council of Europe agreed in November 1961 became part of Article 2b of the SPC and later of Article 53(b) EPC, then of Article 2(2) Biotech Directive and, since the legislator of the EPC 2000 revision did not look into the matter again, also of the EPC 2000.

6.4.2.3 Conclusions

It is clear from the above cited historical documents that the original exception of horticultural or agricultural processes from patentability, which was later removed as being unjustified, was regarded as a provision excepting a whole "class" of inventions from patentability.

As regards the exclusion of essentially biological processes for the production of plants from patentability, no such express statement is to be found in the preparatory documents.

In the legal literature and in the jurisprudence it is often stated that at the time the SPC was drafted it was generally felt that processes for the production of higher life forms and the products thereof involved special problems concerning the criteria for patentability, in particular as regards reproducibility (G 1/98, loc. cit., point 3.4 of the Reasons, p. 130).

This view, however, does not come out explicitly in the preparatory documents.

Furthermore, it does not explain why such inventions were to be excluded from patentability since they would not have been patentable anyway, for lack of reproducibility, or even, as the referring Board has expressed it in T 83/05, for lack of a technical teaching.

As is apparent from the above, the first Preliminary Draft Convention of the EC Working Group of 14 March 1961 already contained an exception from patentability for *"inventions relating to the production of or a process for producing a new plant variety..."*.

Although the explanations given with regard to plants are rather rudimentary, they nevertheless contain some

indication that at that point in time the legislator was concerned with excluding from patentability the processes applied by plant breeders in connection with the creation of new plant varieties, for which a special property right was going to be introduced under the UPOV Convention.

It must be concluded that the legislator's intention was to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time.

These conventional methods included in particular those (relevant for the present referrals) based on the sexual crossing of plants (i.e. of their whole genomes) deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s).

The application of technical means or other forms of human intervention in such processes which helped to perform them was already common.

Nevertheless, the said processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. This phenomenon determined the genetic make-up of the plants produced, and the breeding result was achieved by the breeder's selection of plants having the desired trait(s).

That these were processes to be excluded also follows from the fact that processes changing the genome of plants by technical means such as irradiation are cited as examples of patentable technical processes.

A further teaching is also clearly discernible from the explanations given in the memorandum of the Secretariat of the Committee of Experts for agreeing to the replacement of the words "*purely biological*" by the version still valid today: The exchange of the word "purely" for "essentially" was deliberate and reflects the legislative intention that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a technical character and should not have the effect that such process is no longer excluded from patentability.

The example mentioned at this early stage of development in technologies in the realm of biology, of the use of a special greenhouse for growing a plant, shows that the legislator did not wish breeding processes to be patented in which the technical measures used are only means serving to bring about processes for the production of plants which are otherwise based on biological forces.

This is made abundantly clear by the additional remark in the explanatory notes that such technical devices may perfectly well be patented in themselves but not so the biological process in which they are used.

It can fairly be assumed that even in those relatively early days in the development of plant breeding (as compared with today's possibilities), types of breeding were undertaken in which the use of technical means such as a greenhouse was indispensable in order to make the crossing and growing or selection of certain plants possible. However, no distinction is made in this respect in the explanatory texts. Hence, it can be concluded that this was not a relevant issue for the legislator. On the contrary, the legislator expressly indicates that it was sufficient for such devices to be patentable in themselves.

This is an important point which cannot be ignored for the interpretation of Article 53(b) EPC today.

Certainly, in the meantime the technical means available to influence crossing and selection procedures have increased enormously and become much more sophisticated.

Furthermore, modern technical means may allow crossing and selection procedures which would otherwise not be possible or at least not realistic or economically viable.

However, the clear intention of the legislator behind replacing the word "purely" by "essentially" can even today not be simply ignored, given that the wording of this provision has remained unchanged over time and that not one of the various legislators has apparently seen a need to revise that text.

No doubt one could argue that with such an old law as the exclusion has now become, what the original legislator wished to provide is no longer of such great significance.

Be that as it may, the Enlarged Board is unable to see why the legislator's decision to provide appropriate patent protection for "secondary" features such as technical devices or means (today e.g. markers) by allowing them to be patented in themselves but not to extend protection to the biological process in which they are used, would no longer be justified today, merely because today many more such technical possibilities exist.

On the contrary, given that there is a certain tendency to ever broaden the technical field covered by a patent by drafting claims directed to all envisaged contexts in which the invention might potentially be used, the fact that the legislator did not want such an extension of protection in the field considered here is still a valid consideration to be respected.

Hence, it must be concluded that the provision of a technical step, be it explicit or implicit, in a process which is based on the sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape the exclusion if that technical step only serves to perform the process steps of the breeding process.

This raises the further issue of whether it is justified to distinguish between the application of technical means and other forms of human intervention in the crossing and selection steps which may be important for the performance of the process but are not decisive for the result, in the sense that they are not directly responsible for the insertion of traits into the genome of the plants produced.

Rule 27(c) EPC expressly provides that biotechnological inventions shall also be patentable if they concern a microbiological or other technical process.

Hence, the excluded essentially biological processes stand in juxtaposition to the patentable technical processes.

Considered from the angle of technical character, a form of human intervention utilising the forces of nature (including even the intentional abstention from any intervention) while not being the application of a technical means stricto sensu, can be a measure which is equally as technical (see above under 6.4.2.1).
Thus, in a chemical process, for instance, leaving substances in a vessel for a certain time in order that a desired reaction takes place is a technical measure, even though it is characterized by the - deliberate - abstention from any human intervention.
Similarly, leaving tomatoes on the vine past ripening and determining by looking at them which ones are sufficiently wrinkled for the purpose of enabling or assisting selection of the suitable plants is a technical step, although it is not a technical means stricto sensu which is being applied.
It is, however, a measure involving human intervention, in this case in the context of the selection step.
Human intervention in a process in order to bring about a desired result is the essence of what an invention is, but breeding processes by their nature involve human intervention.
Hence, in more general terms, the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC.
However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability.
Therefore, such a process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.
The above applies only where such additional step is performed within the steps of sexually crossing and selection, independently from their number of repetitions.
Otherwise the exclusion of sexual crossing and selection processes from patentability under Article 53(b) EPC could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from such crossing and selection process.
Any such additional technical steps which are performed either before or after the process of crossing and selection should therefore be ignored when determining whether or not the process is excluded from patentability under Article 53(b) EPC. For the previous or subsequent steps per se patent protection is available.
This is the case, for example, for genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.
As a result this means that, while the presence in a claim of one feature which could be characterised as biological does not necessarily result in the claimed process as a whole being excluded from patentability under Article 53(b) EPC (see 6.2 above), this does not apply where the process includes sexual crossing and selection.

Order

For these reasons it is decided that:
The questions of law referred to the Enlarged Board of Appeal are answered as follows:
1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.
2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.
3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.
4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.
