

When is a process for the production of plants “essentially biological”?

Decisions of the Enlarged Board of Appeal (G1/08 and G2/07)

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In its recent decisions G1/08 and G2/07, which were consolidated, the EPO Enlarged Board of Appeal (EBoA) had to decide on the question of what precisely is to be understood under the exception to patentability set out in Article 53(b) EPC, namely the exemption of “essentially biological” processes for the production of plants from patent protection. The Board had to decide on the questions referred to it by two Technical Boards, T1242/06 (EP 00940724.8; Tomatoes/STATE OF ISRAEL; the “tomato case”) and T83/05 (EP 99915886.8; Broccoli/PLANT BIOSCIENCE; the “broccoli case”).

The cases in question

In T83/05 the subject matter in question was a method for the production of a broccoli plant with elevated levels of 4-methylsulfinylbutyl glucosinolates, and/or 3-methylsulfinylpropyl glucosinolates (substances that are alleged to lower the risk of cancer), said method comprising the steps of:

a) **crossing** wild *Brassica oleracea* species [...] with broccoli double haploid breeding lines;

b) **selecting** hybrids with levels of [glucosinolate(s)], 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 [glucosinolate(s)]; and

d) **selecting** a broccoli line with elevated levels of [glucosinolate(s)], 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 [glucosinolate(s)],

capable of causing a strong induction of phase II enzymes.

Such a technique is also referred to as “marker assisted breeding/selection”.

In T1242/06, claim 1 of the underlying application read:

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.

In both cases the patent proprietors claimed that the methods contain steps of a technical nature (underlined above) that would make those methods escape the provisions of Article 53(b)¹ and Rule 26(5)² EPC. At the very least, the methods would require a level of human intervention that goes beyond what would naturally occur. In case T83/05 the technical board even came to the conclusion that the methods were based on an inventive step and would be patentable under the proviso that they are not exempted from patentability.

The Boards of Appeal handling the respective cases did not see themselves in a position to decide on the allowability of the claims in question. The Board of T83/05 referred the following questions to the EBoA (G2/07):

1. Does a non-microbiological process for the production of plants which

¹ Article 53(b) EPC reads:

European patents shall not be granted in respect of:

- (a) [...];
- (b) plant or animal varieties or **essentially biological processes for the production of plants or animals**; this provision shall not apply to microbiological processes or the products thereof;
- (c) [...].

² The relevant parts of Rule 26 EPC read:

- (1) 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 this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.
- (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.**

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?

The board of T1242/06 referred the following questions to the EBoA (G1/08)

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 non-microbiological 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?

By decision of 21 April 2008, the EBoA decided to consider the points of law of both referrals in consolidated proceedings.

Applicable Law

Prior to addressing the questions referred to it, the EBoA ascertained that the new regulations, Article 53(b) and Rule 26(5) of the EPC 2000 (subsequently EPC³), apply to the instant case and the Board also found that the new regulations are to be interpreted in exactly the same manner as the corresponding provisions under Article 53(b) and Rule 23b(5) of the EPC 1973. In T83/05 the question was discussed whether Rule 25(6) EPC is *ultra vires*, i.e. whether the Administrative Council of the EPO was in fact empowered to decide on substantive patent law, when drafting this regulation in the implementation 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 (hereinafter "Biotech Directive"). This discussion arose because of a conflict between Article 53(b) EPC and Rule 26(5) EPC that will be outlined in more detail below. The EBoA found that the Administrative Council is in fact entitled to implement regulations that concern substantive law and also referred to Article 164(2) EPC, according to which the provisions of the Convention overrule the provisions of the Implementing Regulations in case of conflicts.

Furthermore, the Board found that Rule 23b(5) EPC 1973, which was incorporated into the EPC to take account of the provisions of the Biotech Directive and came into force September 1, 1999, does apply to applications filed prior to its entry into force.

³ References to the EPC 1973 will be indicated as such

Conflict of Rule 26(5) EPC and Article 53(b) EPC

A first problem arises when trying to interpret the exclusion clause of Article 53(b) EPC of "essentially biological processes for the production of plants or animals", as the term "essentially" is open to interpretation. As Article 53(b) EPC is accompanied by Rule 26 EPC, one would seek recourse in this regulation for clarification. The definition given in Rule 26(5) EPC of what is to be understood as an essentially biological process is very narrow, as according to said Rule "a process for the production of plants or animals is essentially biological *if it consists entirely of natural phenomena such as crossing or selection*" (emphasis in italics added). According to Rule 26(5) EPC, thus, a process could escape the exclusion by addition of any minor step of technical nature, while under the wording of Article 53(b) EPC the process as amended could still be excluded.

Also, a literal interpretation of Rule 26(5) EPC would be so narrow that this provision would be pointless since a process with a complete lack of technical character would not qualify as an invention anyway (reasons for the decision, point 6.4.2.3).

Attempts of the EBoA to reach a clarification of the relevance of Rule 26(5) EPC for interpreting Article 53(b) EPC on the basis of the legislative history⁴ of this provision were not fruitful (reasons, point

⁴ Based on the preparatory documents leading to the Biotech Directive, Article 2(2), which was later implemented 1:1 as Rule 23b(5) EPC 1973

Article 2(2) of the Biotech Directive reads:
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.**

4.8.3). Due to the self-contradictory wording of Rule 26(5) EPC, the EBoA even concluded that this Rule is to be disregarded when interpreting Article 53(b) EPC (reasons, point 5) and based its further considerations exclusively on Article 53(b) EPC.

Earlier case law decisions

Prior to the instant decisions, at least two Technical Boards developed a definition of the term "essentially biological process", namely decisions T320/87 and T356/93. In decision T320/87, the Board held that the question of whether or not a process is to be considered as "essentially biological" has to be judged on the basis of the essence of the invention taking into account the totality of human intervention, be it quantitative or qualitative, and its impact on the result achieved. In order to escape the exclusion clause, the human intervention must go beyond a trivial level and its impact on the result must be decisive. Furthermore, the totality of the sequence of the specified operations must neither occur in nature nor be classical breeders' processes. Decision T356/93 added to the above in focussing 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. It explicitly ruled:

"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".

(T356/93 reasons, point 28)

The EBoA voiced its reservations against the definitions of the earlier case law. Primarily, the EBoA considered these definitions flawed since they largely depend on criteria that are linked to the state of the art. Hence, any approach that depends on factors that are more

appropriately assessed by other provisions of the EPC, such as the assessment of inventive step, should not "water down" the questions of patentability. What is non-trivial today, may be commonplace technology tomorrow. Thus, an approach that depends on criteria that may change over time was held to be detrimental to legal certainty. It was also held that in the area of computer-implemented inventions unpatentable non-technical subject matter can be determined without recourse to the prior art.

The EBoA also had reservations towards the further criterion of the totality of human intervention and its impact on the result achieved as defined by T356/93. To this effect, the purpose of the exclusion in Article 53(b) EPC was investigated on the basis of the preparatory documents⁵ of the Strasbourg Patent Convention (SPC) and the EPC 1973.

It was deemed decisive that the change in wording from "purely biological" to "essentially biological" was explained in the preparatory documents as follows:

The processes for the 'production of plants or animals' referred to in the new text include those which may produce known varieties as well as those which may produce new ones, it being understood that only new varieties can eventually qualify for protection in themselves. Selection or hybridisation of existing varieties may be mentioned as examples of such processes (in the vegetable kingdom). The new text specifies that the processes which may be ineligible for patents are essentially (and no longer purely) biological. It was evident that **the exclusion should be extended to cover**

⁵ *Inter alia* Preliminary Draft Convention of the Council of Europe (cf. Doc. EXP/Brev (61) 2 rev. and the memorandum of the secretariat of the committee (cf. Doc. EXP/Brev 61(8), pages 4-5).

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 in growing a plant), it being understood that such technical devices may perfectly well be patented themselves, but not the biological process in which they are used.

(T83/05, reasons point 40, Doc. EXP/Brev 61(8), pages 4-5, original emphasis in underlines, own emphasis in bold)

The above explanation was taken as indication that the purpose of the exclusion was to exclude breeding processes from patentability that were conventional methods for the breeding of plant varieties at that time (for which also a special property right was going to be introduced), irrespective of whether secondary, technical measures were taken in order to assist the fundamental biological processes involved. The essence of the biological phenomena underlying plant breeding processes was defined as the sexual crossing of whole plant genomes and the subsequent selection of plants having the desired traits. Those secondary technical measures *as such* were explicitly deemed eligible for patent protection⁶. Hence, the intention was clearly to prevent arbitrary secondary technical means which do not influence the result of sexual crossing (such as marker analysis to identify co-segregation of desired traits) from "watering down" the intended exclusion of processes that were

⁶ As can be seen from the preparatory documents, steps like irradiation of plants or their seeds with isotopes were considered to represent a technical steps which in themselves would be deemed patentable (if they meet reproducibility requirements). Such a technique nowadays belongs to the standard repertoire of breeders, hence would nowadays be considered as a "classical" breeding method.

fundamentally (essentially) biological. As human intervention is a necessary part of plant breeding processes, the EBoA did not deem it appropriate to make the question of patentability dependant on the kind or extent of human intervention as long as this intervention did not change the essence of the biological processes. Any such human intervention was to be regarded as a "secondary feature" just as the secondary technical features outlined above.

Accordingly, the EBoA held

*"If a process of sexual crossing and selection includes **within it** [i.e. not before or after] 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."* (Reasons Point 6.4.2.3, page 69).

Answers by G1/08 and G 2/07

Based on the above considerations, the EBoA answered the questions of law referred to it 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.

Discussion and practical implications

The ruling marks a break from the existing definitions of the case law decisions T320/87 and T356/93. In the future, methods for producing plants are excluded from patent protection once the method comprises a single step of crossing entire genomes of two breeding partners regardless of the number or importance of further technical measures.

The EBoA decision in fact introduces a marked broadening of the exclusion provision under Art. 53(b) EPC into the practice in the field of plant based inventions. This is basically a change in substance of what is patentable and what is not. This is the more problematic since the EBoA did not provide a transition period of when the new case law should become applicable to patent applications. This in turn means that the new case law

is applicable to any pending patent application as well as granted patents, resulting in a *de facto* invalidation of many protection rights overnight. This decision is in particular harsh when considering that applicants/patentees have almost no chance to manoeuvre in order to save their protection rights in view of the new case law. Method claims comprising one single step of crossing and selection are from now on exempted from patent protection, i.e. invalid. Further taking into consideration that an applicant has very limited possibilities to save his protection right and the patentee having a granted patent has almost no possibility to safeguard his method claims, the decision is to be criticized for not taking this into account. Whereas an applicant might have the possibility to delete the step of crossing and selecting from a claim as long as there is sufficient basis in the original application for such a method (in order to avoid objections under Rule 123(2) EPC for introducing new matter by deleting the crossing and selection step), the patentee finds himself between a rock and a hard place in order to save his method claim. While an applicant might remove the crossing and selection step from the claim if there is a basis for such a broader claim in the original application, such a deletion can no longer be performed in a granted claim since this would broaden the granted claim, which is not admissible under Art. 123(3) EPC. Therefore one may well question whether this decision without any kind of transition period is still in line with the principle of good faith between the applicants and the EPO as stressed in several Enlarged Board of Appeal cases such as G5/88, G7/88 and G8/88.

It also remains a mystery as to why the EBoA decided the way it did. Certainly, the way the EBoA interpreted the term "essentially biological" is not a sound scientific interpretation of this term. There is no scientific basis to disregard any kind of a technical measure in a plant breeding method, and to interpret any method as an

“essentially biological process” as soon as it contains one single step of crossing or selecting is difficult to follow.

If the driving force was to find “a simple solution” to the problem of how to define “essentially biological”, then one may ask why the third answer⁷ was given the way it was. It remains obscure what kind of process might be meant by the process contemplated in this answer, which appears to exempt some type of process from the non-allowable essentially biological processes if the process contains within (not before or after) the steps of sexually crossing and selecting an additional step of a technical nature, which step introduces or modifies a trait in the genome of the plant produced. The third answer also leaves much to be desired in the way of clarity. What exactly is a trait? How is one to determine whether a given action modifies a trait and is clearly not the result of mixing of genomes (there are various “exceptional” but natural events that lead to alterations of traits). What does the expression “within the steps of sexually crossing and selection” mean in practice? Does that imply that a (hypothetical) process in which one first performs the crossing and introduces or modifies a trait prior to selection is eligible for patent protection, while the same process, in which the same modification is

made in both of the parent plants before sexual crossing and selection is not?⁸

Hence, the answer given by the EBoA does not simplify, but rather complicates the interpretation of the exemption under Art. 53(b) EPC.

Finally, if the intention was to protect plant breeders and farmers from being attacked by process patents, it would have been much more reasonable to prevent process patents containing only “trivial technical features” in addition to the crossing and selecting step by rejecting such claims under Art. 56 EPC (lack of inventive step), rather than trying to fix this problem by an extensively broad interpretation of the exemption under Art. 53(b) EPC. The problem of how to avoid the grant of such method claims could be done by a reasonable application of Art. 56 EPC for assessing inventive step. Only the features in the claims that are considered non-biological i.e. the steps in addition to crossing and selecting steps, could be considered in the assessing of an inventive step. This would mean that only trivial features in addition to the crossing and selection step should lead to the rejection of the claim for lacking an inventive step. Alternatively, if the further technical measures in a method claim would indeed be more than trivial measures, the granting of such a patent would be fair to the patentee but would still not be a risk for a plant breeder or farmer performing only the crossing and selection step. For a patentee having a granted patent where the granting is based on the technical measures in the claim, it would be impossible to enforce such a claim against a plant breeder not making use of the technical measures in the claim but

⁷ “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 Art. 53(b) EPC”.

⁸ The feedback we have received from plant geneticists and plant breeders is that they do not understand what should fall under the “exemption from the exemption” formulated in the third answer of the EBoA.

only applying the crossing and selection steps. On the other hand, if the breeder would also make use of the further technical measures in the claim which formed the basis for allowance, why should the breeders then be exempted from the effects of a granted patent? Such an approach of considering only some measures of a claim for assessing patentability would not be a new concept. Rather, this is already applied for claims containing technical and non-technical features; where it is determined whether a given method is a technical teaching (i.e. invention) or rather a non-technical process not regarded as an invention in the sense of Art. 52 EPC. This would be analogous to the approach of the EPO adopted in relation to mathematical methods and computer-related inventions, which *as such* do not form patentable subject matter but which allow patents on overall technical processes even if they do contain steps relating to mathematical methods (e.g. T 208/84 (OJ 1987, 14), or T 1161/04).

With the decision as it now stands, the question is: What are applicants' options in order to still get patents for the pending applications in this field?

A first option is of course to avoid (or delete) a crossing and selecting step in a method claim. This of course requires that there is sufficient basis in the application as filed for such a broadening of the claim. If this is not possible for lack of sufficient support and hence in conflict with Art. 123(2) EPC, one may have the following options in order to achieve an allowable claim.

Applicant may try to draft product-by-process claims, wherein the plant to be prepared is characterized by its steps of preparing same. The EBoA case did not address the question of patentability of a product obtained by an "essentially biological process". Hence, a product-by-process claim should still be an option in order to obtain patent protection for some

embodiments in this field. Of course, for such a claim one would also need to show a basis in the original application for such a product.

Alternatively, a claim might also be directed to the immediate product of a process claim which, for the same considerations as explained above for the product-by-process claim, should not be excluded from patent protection as now decided for the essentially biological processes. Such a claim might be less critical with regard to sufficient support in the original description. According to established case law, a process for preparing a product discloses the product as such even in the case of lack of explicit mention of the product in the application (see e.g. T93/93 and T1080/01). It remains to be seen how the future case law will handle the question of patentability of a product obtained by an essentially biological process.

Last but not least, one might give a disclaimer a chance, where the case law of the Enlarged Board of Appeal allows delimitation of a claim by way of disclaimer via an exclusion provision (e.g. G1/03). Such a measure might be taken if there is no possibility for amending a method claim by deleting the crossing and the selecting step or by rewording the same into a product claim. As is clear from the above, there are a few options left for the applicant in order to overcome the obstacles now created by the EBoA case, but it remains to be seen how the EPO will deal with such claim amendments in future decisions.