Correct legal interpretation of Article 53(b), EPC, regarding the patentability of essentially biological processes in relation to plants and animals within the context of the EU patent directive 98/44

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Summary

In 2015, the Enlarged Board of Appeal (EBoA), in its combined G 2/12 and G 2/13 decisions, declared plants derived from essentially biological processes to be patentable.

However, in 2016, the EU Commission provided evidence that these EBoA decisions needed to be revised. This is of legal relevance for EPO decision-making: Since Rule 26(1) EPC states that the EU Biotechnology Directive 98/44 shall be used as a supplementary means of interpretation when applying and interpreting the relevant provisions of the EPC, the intention of the EU legislator has a binding effect on the interpretation of Rules 26-29 included in the EPC. As the 'EU Commission Notice' shows, the G 2/12 and G 2/13 decisions do not correctly interpret the intention of the EU legislator. The need to correct G 2/12 and G 2/13 was confirmed in further decision-making by EU member states as well as in the establishment of national patent legislation.

In 2017, the Administrative Council, after considering the 'EU Commission Notice' and other decisions taken by the EU Parliament and the Council of Ministers, re-examined the G 2/12 and G 2/13 decisions. The intention of the EU legislator was explicit and the Council concluded that plants and animals derived from essentially biological breeding cannot be regarded as patentable inventions. To achieve clarity, a new Rule 28(2) was established for interpretation of Article 53(b).

In 2020, the Enlarged Board of Appeal (G3/19), after a request from the President of the EPO, confirmed the applicability of the new Rule 28(2). However, the effects of the change in Implementing Regulations (Rule 28(2)) were restricted to patent applications filed after 1 July 2017. The reason: the Enlarged Board of Appeal interpreted the development within the EU as a dynamic process which resulted in a new interpretation of patent law at the end of June 2017.

However, as detailed legal analysis shows, the legally binding effects of EU law regarding the interpretation of Article 53(b) that negatively affect the allowability of claims directed to plants, plant material or animals derived from essentially biological processes, are not tied to the date when Rule 28(2) came into force. In fact, the intention of the EU legislator has not changed since the EU patent directive came into force, and the EU legislator never intended to allow patents on plants and animals derived from essentially biological processes.

Therefore, if the logic of decision G3/19 decision is followed based on the correct interpretation of EU patent law, it does not matter whether the patent applications were filed before or after July 2017. Plants and animals derived from essentially biological processes clearly cannot in general be regarded as patentable inventions.

In addition, it is evident that when previous Enlarged Board of Appeal decisions (G2/07 and G1/08) are taken into account, only technical processes which "*by itself introduce a trait into the genome"* can generate patentable inventions. This is in accordance with the interpretation of EU patent law provided by the EU legislator. Consequently, random genetic changes (mutagenesis) or other non-targeted methods used in conventional breeding must be regarded as 'essentially biological' and are therefore excluded from patentability.

Finally, in order to provide sufficient clarity and certainty regarding the intended effects of Article 53(b), it follows that the scope of patents falling within the criteria of Article 53(b) must be restricted to the technical processes as described in the patent.

1. History of European patent law in regard to patents on plants and animals

For the correct interpretation of Article 53(b), it is important to be aware that it was EU Directive 98/44 which paved the way for patents on inventions covering plants and animals.

The European Patent Office (EPO) had already granted some patents on plants before the introduction of genetic engineering and the Directive. There is, however, no indication in the wording of the European Patent Convention (EPC) adopted in 1973 that the legislator at that time intended to allow patents on plants and animals in general.

A historical examination including legal comments published during the first fifteen years after the EPC came into force, shows that, for example, standard commentaries (such as well-known commentaries by BENKARD, Patentgesetzkommentar, 8. Auflage (1989), BECK; Schults Patentgesetzkommentar, Heymanns, 2.-4. Auflage, (1987); SINGER, Europäisches Patentübereinkommen, (1989), Heymans) came to the conclusion that plants and animals were not generally patentable.

The same conclusion can be drawn from legislation adopted by the Contracting States when the EPC was transposed into national legislations. In Switzerland, for example, when national patent law was adopted in 1976, the Swiss Bundesrat made a statement clearly showing that plants and animals were regarded as non-patentable: *"([Es] können nicht patentiert werden: auf dem Gebiet des Pflanzen- und Tierreichs: die Lebewesen selbst."*) A similar comment can be found in the German Bundestagsdrucksache Nr. 8/2087 of 7 September 1978, which concerns the interpretation of German patent law.

Despite this legal framework, the EPO granted some patents on plants in the 1980s and 1990s. It appears that at least some examiners at the EPO believed - contrary to the references above – that patents on plants could be granted. As decisions T 356/93 and T1054/96 show, this issue was still not settled when Directive 98/44 was adopted.

The oppositions and appeals against the oncomouse patent (which was the first patent on a mammal in Europe), T0315/ 03 and decision G1/98 (genetically engineered plants), were only finally decided after the EU Directive was adopted and had become part of the Implementing Regulations of the EPC. Thus, G1/98 and T 0315/03, may be seen as precedents in this field, but cannot be interpreted as decisions made independently of the wording of the EU Directive. It was the EU Directive 98/44 that paved the way for a new interpretation of the EPC and was used by the EPO to

grant patents on genetically engineered plants and animals.[1]

In summary, the question to which extent plants and animals are patentable under the EPC was not finally decided until the EU patent directive 98/44 was adopted and Rules 26-29 EPC became an integral part of the EPC in 1999. Therefore, the EPC as adopted in 1973, cannot be interpreted to mean that patents on plants and animals were generally allowed. It was only after the EU Directive was adopted and became part of the Implementing Regulations that the EPC was applied as it is currently. Consequently, the EU Directive has been decisive for the interpretation of Article 53(b) EPC since 1999.

2. The context of Article 4 of EU Directive 98/44

Article 4 of the EU patent directive 98/44 concerns the prohibitions in patent law regarding plant and animal breeding. The wording of the article corresponds with Article 53(b):

> *"1. The following shall not be patentable:*
>
> *(a) Plant and animal varieties;*
>
> *(b) Essentially biological processes for the production of plants or animals.*
>
> *2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.*
>
> *3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process."*

This needs to be put into context in order to clarify the scope of Article 4 of EU Directive 98/44. As the title of the Directive 98/44 (Legal Protection of Biotechnological Inventions), and the wording of the Recitals 52 and 53 of the Directive show, it was not the legislator's intention to allow the patentability of products obtained from essentially biological processes. It should be noted that at the time when the Directive was being discussed, and voted on, in the EU Parliament, the European Patent Office (EPO) had officially stopped granting patents on plants and animals because of decision T356/93 made in 1995.

Thus, in adopting Directive 98/44, members of the EU parliament as well as EU member states and the EU Commission, paved the way for harmonised patent protection intended only for plant-related inventions in the context of genetically engineered plants and animals. Indeed, the EU Directive led to a significant shift in current practice at that time. It was only after the Directive was adopted and had become an integral part of the new Implementing Regulations of the EPC in 1999 – in the context of an Administrative Council of the European Patent Organisation decision - that the EPO resumed granting patents on plants and animals derived from genetic engineering.

It can be assumed that in adopting Directive 98/44, the legislator did indeed intend to regulate patents on plant-related inventions stemming from genetic engineering. At the same time, there is nothing to indicate that the legislator wanted to allow patents on plants and animals derived from essentially biological processes used in conventional breeding as a general rule.

It can be concluded, that all processes in conventional breeding as well as all products (plants, animals, their characteristics, their genetic components, seeds, breeding material, gene sequences) are excluded from patentability under Directive 98/44.

[1] It should be noted that the EU Directive does not explicitly request patents on plants and animals, but only on "inventions which concern plants or animals".

3. Recent interpretation of EU patent law by the EU legislator with binding effect for the interpretation of Article 53(b)

The above findings are supported by more recent statements, decisions, resolutions and conclusions made by the EU legislator in regard to plants and animals derived from essentially biological processes: from the first time this issue was explicitly brought to the attention of the EU legislator in 2012, all the EU legislative institutions have had a consistent and clear line of interpretation. There is no doubt that the EU legislator never intended to allow patents on plants and animals derived from essentially biological process for breeding when adopting the EU Directive 98/44. It should also be noted that no case was ever brought before the European Court of Justice to challenge or even contradict this coherent line of interpretation.

In May 2012, a European parliament resolution urged the European Commission "*to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding*" and requested "*the so-called whole content approach*" to be applied to the interpretation of current provisions in European patent law (*EP Resolution on the patenting of essential biological processes, 10 May 2012 (2012/2623(RSP))*. [2]

In a December 2015 resolution, the EU Parliament requested the EU Commission "*as a matter of urgency, to clarify the scope and interpretation of Directive 98/44/EC, and in particular Articles 4 12(3)(b) and 13(3)(b) thereof, in order to ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes, and to clarify that breeding with biological material falling under the scope of a patent is permitted*." [3]

In November 2016, the EU Commission adopted Notice C/2016/6997 on certain articles of Directive 98/44/EC of the European parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ("EU Commission Notice"), which was subsequently published in the Official Journal of the EU.[4] Based on an analysis of the travaux préparatoires relating to the adoption of the EU Biotechnology Directive, particularly concerning Article 4, as well as on an interpretation of other provisions of the EU Biotechnology Directive, the EU Commission takes the view that the EU legislator's intention when adopting the EU Biotechnology Directive was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes.

In a meeting of 20 February 2017, the Council of the EU/Competitiveness Council adopted conclusions welcoming the EU Commission Notice, recalling that the EU legislator's intention when adopting the EU Biotechnology Directive had been to exclude from patentability products obtained through essentially biological processes, and urging member states to advocate that the practice of the EPO be aligned with the EU Commission Notice.[5]

As a result, the three institutional legislative bodies of the EU, i.e. the Parliament, the Commission and the Council, all agreed on the interpretation that there was no intention on the part of the EU legislator to allow patents on plants and animals derived from conventional breeding (essentially biological processes).

Rules 26-29 EPC became an integral part of the EPC in 1999 in order to implement the requirements of the EU Biotechnology Directive in European patent law. Rule 26(1) EPC states that

[2] https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html?redirect
[3] https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html?redirect
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478769496064&uri=CELEX:52016XC1108(01)
[5] https://data.consilium.europa.eu/doc/document/ST-5808-2017-INIT/en/pdf

the EU Biotechnology Directive 98/44 shall be used as a supplementary means of interpretation when applying and interpreting the relevant provisions of the EPC. Therefore, the intention of the EU legislator also has a binding effect from the point in time when Rules 26-29 became part of the EPC.

This legal situation did not change when the new Rule 28(2) was included, as assumed in the G3/19 decision. Rather, independently of the date when Rule 28(2) came into force, the intention of the EU legislator has to be taken into account for all patent applications filed after the Rules 26-29 EPC were included in the EPC (in 1999).

While the intention of the EU legislator was made explicit in 2012, 2015, 2016 and 2017, this intention in no way is restricted to any specific date after 1999. Rather, this intention already existed and was legally binding as soon as the EU patent directive 98/44 was adopted.

In fact, the intention of the EU legislator has not changed since the EU patent directive came into force. It is evident that the EU legislator never intended to allow patents on plants and animals derived from essentially biological processes.

Therefore, the explicit intention of the EU legislator over the last ten years is legally binding for the examination of all patents filed after the Rules 26-29 were included in the EPC.

4. The definition of essentially biological processes

As can be seen from the history and the context (above), it is evident that EU patent directive 98/44 would not have arisen without the (at that time) new methods of genetic engineering. This technology has for the first time allowed direct and specific technical intervention to directly insert a trait. Therefore, the ‘EU Commission Notice’ correctly states that Article 4 of the Directive only allows patents on inventions involving genetic engineering of plants and animals, e.g. “for instance the insertion of a gene into a genome“.

In its G2/07 and G1/08 decisions, the EBoA provides a definition of essentially biological processes which correlates with the EU Commission interpretation. In particular, the criterion to directly insert a trait, as developed in G2/07 and G1/08, is equivalent to the ‘EU Commission Notice’.

The headnotes of these combined EBoA decisions read (emphasis added):

“*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." (emphasis added)

In order to assess whether a technical step can render the overall process eligible for patent protection, the Enlarged Board of Appeal, in its G2/07 and G1/08 decisions, gives the following criteria: "*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."* (emphasis added)

Accordingly, what is needed to overcome the prohibition in Article 53(b) is a technical step within the process that directly and purposefully establishes a desired trait (defined phenotype) in the genome, and makes it therefore fundamentally different to methods of conventional breeding. In this regard, a clear technical distinction between 'essentially biological' processes (conventional breeding) and technical interventions (old and new methods of genetic engineering) can easily be made, as shown below:

(1) Essentially biological processes:

Conventional breeding starts from a broad range of genetic diversity, followed by further crossing and selection. If methods such as irradiation are used, this does not change the overall process in the sense of Article 53 (b). In general, physico-chemical mutagenesis just triggers genomic changes in a non-targeted way to enhance genetic diversity in the plant material, which is needed for further steps of crossing and selection. To derive a desired trait (phenotype), for example, after irradiation, crossing and selection will always be needed to eliminate undesirable mutations (by segregation), and to introduce the desired mutations into a favourable genetic background. This genetic background should typically allow a high expression of the desired mutations in absence of genetic characteristics which negatively interfere with the biological characteristics of the intended phenotype. Therefore, to establish a desired trait after irradiation, the claims will always, explicitly or implicitly, include sexual crossing and selection processes. In conclusion, by introducing such a step, the overall process still cannot escape the prohibition in Article 53(b) and Rule 28(2). There is no doubt that, in light of the G2/07 and G1/08 decisions, such processes must still be considered 'essentially biological'.

(2) Technical processes:

On the other hand, technical methods of genetic engineering involve the insertion of additional DNA sequences or the usage of biotechnological mutagens, and therefore allow the direct and targeted change of specific genes in the genome. These techniques not only result in alterations of the genome, but enable direct introduction of defined biological characteristics (phenotypes), so-called 'traits', in existing varieties. To achieve its goal, genetic engineering typically uses genetic constructs consisting of promotors, start and stop codons and gene sequences optimized for expression in the plant cells. Furthermore, genome engineering techniques can also introduce specific and targeted changes in the genome by using biotechnological mutagens, such as CRISPR/Cas. These techniques can typically eliminate the steps of crossing and selection needed to establish a desired trait.

Genetic engineering might still require crossing and selection to establish the trait in specific varieties. However, this further breeding, will typically not change the biological characteristics of the intended phenotype. Therefore, these genomic techniques can be considered to fulfill the criteria established in the G2/07 and G1/08 decisions, while processes using steps, e.g. irradiation, cannot escape the prohibitions in Article 53(b) and Rule 28(2).

These findings are illustrated in Figure 1:

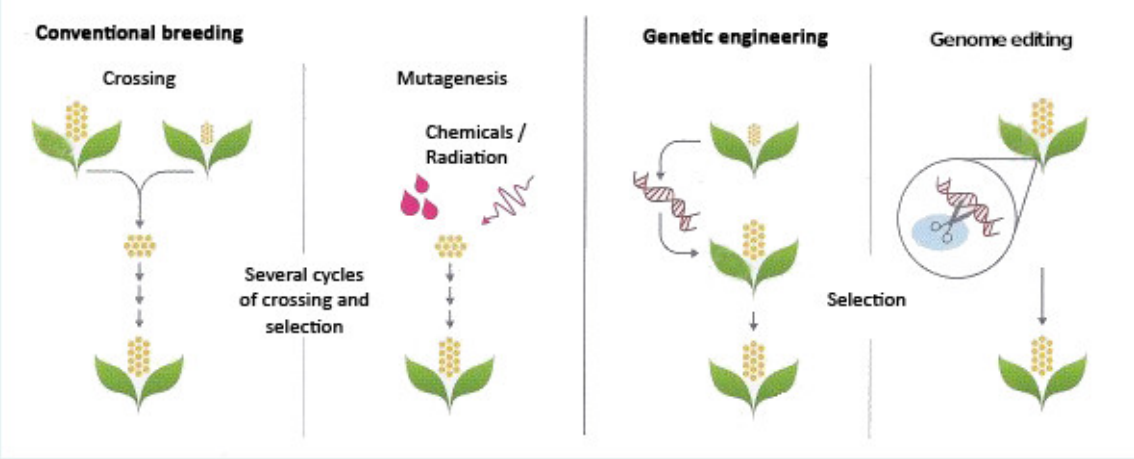


Figure 1: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new characteristics into a plant (adopted from Genomxpress Scholae Nr 5, funded by the German Ministry for Education and Research (BMBF).

The Enlarged Board of Appeal decisions G2/07 and G1/08 as well as the 'EU Commission Notice' all show that (contrary to what was assumed by the Administrative Council document, CA/56/17[6]) that random genetic changes (mutagenesis) or other non-targeted methods used in conventional breeding, have to be regarded as essentially biological and must therefore be excluded from patentability.

In conclusion, in order to uphold the EU patent directive and its effects on the interpretation of Article 53 (b), all exemptions to the exception to patentability of Article 4(1) should be contextualised, thus precluding the application of the 'confinement' and 'technical feasibility' criteria to conventional breeding. The concept of 'essentially biological' should be more clearly defined, with reference to the ability to directly insert a desired trait into the genome of a plant or animal with a targeted technical processes.

[6] www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf

5. Conclusion and recommendations

According to the analysis provided, there are three crucial findings in regard to the correct legal interpretation of Article 53(b), EPC, in the context of the EU patent directive 98/44:

1. Definition of ‘essentially biological processes’

The exclusion of ‘essentially biological processes’ covers all conventional breeding processes, including random mutagenesis, as well as all individual steps in the process, such as selection and / or propagation.

2. ‘Products’ used or derived from breeding

All ‘products’ used in or emanating from ‘essentially biological processes’ are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information. This exclusion is effective independently of the date when Rule 28(2) came into force.

3. The scope of protection

In the context of plant and animal breeding, the EPO must not grant ‘absolute product protection’, which enables a patent on a plant or animal derived from a technical process to be extended to all conventionally bred plants with the same traits.