The correct interpretation of Rule 27 (b), EPC, and the patentability of plant varieties

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Rule 27 (b) of the European Patent Convention (EPC) is based on Article 4 of EU patent directive 98/44 (Legal Protection of Biotechnological Inventions). The wording of the Article is:

> *"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 document explores the history of the rule and provides legal expertise to ensure effective and meaningful exclusions from patentability of Article 53 (b) and Rule 27 (b) in regard to plant varieties.

1. History of European patent law and the European Patent Convention

Contrary to the opinion of some experts, there is no legal obligation under the European Patent Convention (EPC) that requires the granting of patents on plants and animals. It is important to be aware of this legal situation since it is decisive for the history and interpretation of EU Directive 98/44.

Indeed, to some extent, the European Patent Office (EPO) was already granting 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 in general, plants and animals were not patentable.

The same conclusion can be drawn from legislation passed by Contracting States when the EPC was transposed into national legislations. In Switzerland, for example, in 1976, when national patent law was adopted, 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 question was still not settled when Directive 98/44 was adopted.

The oppositions and appeals against the patent on the oncomouse (which was the first patent on a mammal in Europe), T0315/ 03 and decision G1/98 (genetically engineered plants) were finally decided after the EU Directive was adopted and had become part of the Implementation Regulation of the EPC. Thus, G1/98 and T 0315/03, which can be seen as precedent cases in this field, 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]

To summarise, 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 taken into the Implementation Regulations of the EPC. The EPC as adopted in 1973, however, 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 Implementation Regulations that the EPC was applied as it is currently.

In conclusion, the current interpretation of the EPC could be changed to exclude patents on plants and animals - at least those derived from conventional breeding - without coming into conflict with the original intention of the EPC.

2. Exceptions to Patentability: Article 4.2 of EU Directive 98/44

To clarify the scope of Article 4.2, it has to be put in context. 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 Parliament, as well as the 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 Implementation Regulations of the EPC in 1999 by a decision of the Administrative Council of the European Patent Organisation that the EPO resumed granting patents on plants and animals derived from genetic engineering.

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

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 also the EU Directive does not explicitly request patents on plants and animals, but only on “inventions which concern plants or animals”.

As aforementioned, Article 4.1 (a) prohibits patents on plant varieties while Article 4.2 allows patents on inventions concerning plants or animals if the technical feasibility of the invention is not confined to a particular variety.

This exemption from the exclusion (Art 4.2) provides the main justification for the European Patent Office (EPO) to currently grant patents on plants and animals derived from genetic engineering. The exemption is part of the Implementation Regulation of the European Patent Convention (Rule 27 (b)). This legal approach was used in the G1/98 decision made by the Enlarged Board of Appeal, which is seen as the precedent case for the patenting of genetically engineered plants and animals under the EPC, ruled upon shortly after the inclusion of the EU Directive 98/44 in the Implementation Regulation of the EPC.

In the field of conventional breeding, the exemption from the exclusion (Art 4.2) cannot be used to allow patents on all plants and animals for several reasons:

(1) As a general rule, this exemption cannot be applied to conventional breeding, since the whole rationale of the EU Directive is directed to “biotechnological inventions” and thus to the field of “genetic engineering” (see point above).

(2) If the “technical feasibility” (which should not be confined to a particular plant variety to fall under patent protection) is put in context of the processes for genetic engineering, which enables the transfer of DNA sequences, for example, beyond the boundaries of species, the exemption from the exclusion (Art 4.2) develops a specific meaning. However, in conventional breeding most plant characteristics can be transmitted to any other variety within the same species, just by further breeding, without using a specific technology. As a result, the criterion retained in Article 4.2 and applied by the EPO to restrict the exception to patentability, does not have a specific technical meaning and does not provide any legal clarity in the context of conventional breeding. To summarise, from a technical point of view, the criterion of “confinement of the technical feasibility of the invention to a particular plant or animal variety” can hardly be applied in the field of conventional breeding.

(3) In general, the overlap between plant variety protection and patent protection is much stronger in the context of conventional breeding in comparison to patents granted in the field of genetic engineering. If the provisions of Article 4.2 are applied to plants derived from conventional breeding in the same way as they are applied to genetically engineered plants, the prohibition of patenting plant varieties will become meaningless. In this case, patents will also be granted on plants if they have characteristics that can be transferred easily to other plant varieties by crossing and selection and do not require technical means that can overcome the barrier between species.

3. Conclusions

In the case of conventionally bred plants and animals, the prohibition of Article 53 (b) is not limited by Article 4.2 of the EU patent directive. As a result, plants and animals derived from conventional breeding cannot and should not be regarded as patentable. The exception of Rule 27 (b) can not be applied in the case of conventionally bred plants.