

no patents on seeds

Technical briefing: How should the exclusions in Article 53(b) be interpreted to make them effective?

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1. Introduction

In November 2016, the EU Commission published an explanatory notice on some specific articles in EU Directive 98/44. Significantly, the EU Commission takes the view that plants and animals obtained by means of “essentially biological processes” for the breeding of plants and animals are non-patentable.

This latest statement echoes demands made by the EU Parliament and reflects the position of several European governments, such as Austria, Germany, the Netherlands and France. In these countries national patent laws have already been changed to prohibit patents covering plants and animals derived from “essentially biological” breeding.

The EU Patent Directive as well as the European Patent Convention (EPC) prohibit patents on “plant and animal varieties” and on “essentially biological processes” for the breeding of plants and animals. However, these prohibitions have been extensively eroded by the current practice of the European Patent Office (EPO). The EPO continues to grant patents on plants derived from conventional breeding e.g. on tomatoes and broccoli. This has led the organisations in the international coalition of *No Patents on Seeds!* to be seriously concerned about the policy of the EPO and its impact, namely the increasing monopolisation of seed and food production.

Political decision-makers must now ensure that the EPO adopts the EU notice, and that this new interpretation of patent law becomes legally binding. Most importantly, the Administrative Council of the European Patent Office should include relevant provisions into the Implementing Regulations to the EPC.

There are three problems that need to be addressed by the Member States of the EU and the Administrative Council:

1. The exclusion of plants and animals derived from conventional breeding must become legally binding.
2. The definition of “essentially biological processes” should cover the whole area of conventional breeding.
3. The scope of patents should be limited to avoid overlap between patentable and non-patentable inventions.

The following sections outline some reasons and suggestions for changes in the text of the Implementing Regulations to ensure that exclusions in Article 53(b) become more effective and to ensure more legal certainty and clarity.

2. The legal provisions

Article 4 of EU Directive 98/44/EC and Article 53(b) of the European Patent Convention (EPC) exclude

“essentially biological processes for the production of plants or animals.”

The following definition was initially included in Article 2 (2) of EU Directive 98/44/EC and was subsequently adopted as part of the Implementing Regulations of the EPC (Rule 26 (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.”

3. EPO interpretation: Patentability of the processes

The European Patent Office (EPO) forwarded several questions to the Enlarged Board of Appeal (EBA) after finding that the definition in the EU Directive was very difficult to apply in legal practice.

In 2010, in its decisions G1/08 and G2/07, the EBA argued that processes containing or consisting of the steps of crossing and selecting should be excluded from patentability as being “essentially biological”:

“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.

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.”

It should be mentioned that this definition is not fully in line with the provisions of Article 2 (2) of EU Directive 98/44/EC and Rule 26 (5), EPC. While the legal provisions exclude methods such as “crossing or selection”, the decision of the EBA speaks about crossing (...) and of subsequently selecting” which is likely to narrow the scope of the exclusion.

In addition, what is patentable was defined as follows:

“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.”

As a result, the EPO continues to grant patents on methods of genetically engineered plants and animals because those processes are considered to be a *step of a technical nature*, “which step by itself introduces a trait into the genome”.

However, there are several grey areas. For example, random mutagenesis – from the perspective of patent law - is not really 'technical' because the changes in the genome are not introduced by specific technical means, but are random. Nevertheless, according to the definition implemented by the EBA, it could be considered to be a *step in itself to introduce or modify a trait into the genome*

without crossing and selection. Further processes that allow the propagation of plants (such as usage of shoots) or the selection of plant characteristics without crossing (such as selection of native traits) might still be considered to be patentable.

Two recent examples from EPO case law exemplify these grey areas:

- EP 2134870 held by Monsanto covers selection of soybeans for the purpose of further breeding. During the opposition procedure, the EPO, in December 2016, published a preliminary opinion stating that the selection of plants for further breeding can be covered by patents: "... the decision G1/08 does not allow to draw the conclusion that methods for the selection ... of plants based on markers (or any other feature such as oil content, or pathogen resistance) would be excluded from patentability.". According to the examiners, only selection in combination with crossing will be excluded – this is not in accordance with the wording of the EPC (see above).
- Patent application EP 2571347 filed by Rijk Zwaan claims cucumbers derived from random mutagenesis. During the examination, the EPO, in December 2016, suggested that the company should explicitly state that the plants are derived from random mutagenesis "otherwise, the proceedings may have to be stayed" because the processes would be regarded as "essentially biological".

These cases show that the examiners at the EPO are looking for loopholes and grey areas in decisions G2/07 and G1/08 so that they can continue to grant patents on conventional plant breeding. So far, it appears that the EPO has not finally decided how it will apply G2/07 and G1/08. Whatever the case, there is, as yet, no legal certainty or clarity.

4. EPO interpretation: Patentability of products

In further decisions (G2/12 and G2/13), the Enlarged Board of Appeal at the EPO decided that plants and animals derived from "essentially biological" breeding can be patented, even though the process is excluded under Article 53(b), EPC.

5. EU Commission interpretation

In November 2016, the EU Commission drew up an explanatory notice on the interpretation of Article 4 of EU Directive 98/44/EC. In its conclusion it states that:

"the Commission takes the view that the EU legislator's intention when adopting Directive 98/44 /EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes."

This explanatory statement is in clear contradiction to the decisions of the Enlarged Board of Appeal at the EPO (G2/12 and G2/13).

Since 1999, when the EPO adopted the provisions of EU Directive 98/44/EC, the EPO has to some extent been bound by the interpretation of the institutions of the EU in regard to its specific articles. Consequently, there is now an expectation that the EPO should adapt its legal practice in accordance with the interpretation presented by EU institutions.

Further, the EU Commission – based on the history and the text of the EU Directive - also presented some guidance on what is regarded as patentable:

“The trigger point for ensuring the patentability of either a plant or an animal is the technical process, such as for instance the insertion of a gene into a genome. Essentially biological processes are not of a technical nature and therefore, according to the position taken by the legislator, they cannot be covered by a patent.”

This interpretation at least partially diverges from the one given by the EPA in G2/07 and G1/08.

In general, the definition provided by the EU Commission follows the distinction between genetic engineering and conventional breeding. It clearly defines the technicality of methods which are patentable: The meaning of the expression “insertion of a gene into a genome” as a method used in genetic engineering can be understood historically (in regard to Directive 98/44/EC), and also technically and legally, for example, EU Directive 2001/18 and its predecessor Directive 90/220/EEC are based on a similar definition for genetically modified organisms that need to be regulated.

Indeed, Directive 98/44/EC in Recitals 1, 2, 52 and 53 as well as in Article 16 uses the expression “genetic engineering”. Further, in Recital 32 the expression “genetic modification” is used and Recital 9 and 10 deal with “biotechnology” in the sense of genetic engineering. This wording – and the history of the Directive – clearly shows that the EU intent is to allow patents on methods of genetic engineering, but not on methods applied in 'conventional' breeding. From the perspective of patent law – which is not directly linked with the regulation of genetically engineered organisms – it can be followed that the decision G2/07 and G1/08 of the Enlarged Board of Appeal should be understood as follows: Only if material inserted from outside into the cell 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 targeted and not derived at random, then the process is not excluded from patentability under Article 53(b) EPC.

Therefore, the guidance drawn up by the EU Commission provides more legal certainty and clarity than the one previously developed by the EBA (G1/07 and G2/08). It is derived from the context and the history of the EU Directive. Consequently, there now has to be an assumption that the EPO will adapt its legal practice accordingly.

6. Further clarifications

There are further legal uncertainties that will need more clarification. In particular, both the scope of patents and the prohibition relating to granting patents on plant and animal varieties need further consideration.

a) Scope of patents

If 'absolute product protection' is provided for plant and animals produced by methods of genetic engineering, then the scope of these patents can also cover plants and animals derived from “essentially biological processes” with the same or similar characteristics.

Therefore, to make the exclusion in Article 53(b) effective, the scope of patents should be restricted to the technical method used to produce plants or animals. This problem - to some extent - can be resolved in national patent law. For example, Article 10 of French legislation on biodiversity (Loi pour la reconquête de la biodiversité, de la nature et des paysages) prohibits the extension of the protection conferred by patents on “*a biological material possessing specific characteristics as a result of the invention*” to plants or animals derived from “essentially biological processes” and naturally containing the same traits.

Since national law might not lead to a harmonised approach and might, therefore, not provide sufficient legal certainty and clarity, the EPO should generally avoid granting patents on inventions concerning plants and animals that provide 'absolute product protection'. Instead, only 'process claims' should be granted.

It is important to note that patent protection on products can also be derived from 'process claims', since the result of the process is also covered by the patent. However, so-called 'absolute product protection' is based on 'product claims' and goes beyond process-bound patent protection: If a 'product claim' is granted, the scope of the patent will cover all products (plants or animals) with same or similar or identical characteristics as described in the patent – independently of the method by which they were produced.

Consequently, if 'process claims' are granted on methods of genetic engineering, then plants and animals obtained by these methods will fall within the scope of the patent as well as their offspring as long as they contain the patented functions (traits). However, plants and animals with similar or identical characteristics obtained by means of *essentially biological* breeding, will not fall within the scope of the patents.

As the following analysis shows, the EU Directive and the EPC do not request 'absolute product protection' for inventions concerning plants and animals. Especially relevant in this context is Article 4 of Directive 98/44/EC, which is specific for the patents granted under Article 53(b) of the EPC. Further, Article 3 of the EU Directive might be considered as being relevant, even though this article is more important for material used for pharmaceutical purposes.

Article 4.2 of EU Directive 98/44/ EC (and Rule 27 (b) of the EPC) reads

“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.”

While patent protection for inventions concerning plants and animals is requested, the wording of this paragraph does not compel 'absolute product protection' for the resulting plants and animals. Therefore, patentability can be fully satisfied by process claims. The same analysis can be applied to Recital 32.

Further, Article 4.3 requests patent protection in regard to:

“inventions which concern a microbiological or other technical process or a product obtained by means of such a process.”

This provision is related to the wording of Article 53(b), EPC, which reads in full length:

*“European patents shall not be granted in respect of:
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.”*

In the past, this article has caused considerable confusion and uncertainty in regard to the patentability of plant varieties. However, this was dealt with in the G1/98 decision of the Enlarged Board of Appeal on the patentability of plant varieties: The EBA decided that the term “microbiological processes” is not of relevance for the prohibitions under Article 53(b). In its G 1/98 decision the Enlarged Board of Appeal states:

“Genetically engineered varieties were covered by the prohibition on granting patents for

plant varieties under Article 53(b) EPC even if the variety should in some sense be considered the product of a microbiological process”

The reasoning for the decision G1/98 is somewhat loosely termed and can only be applied to plant and animal breeding in general:

“At the time the Strasbourg Patent Convention and the EPC were drafted, it was inconceivable that varieties could be obtained with the help of techniques including microbiological steps. Thus, the legislator could not have intended that plant varieties should be patentable as products of microbiological processes.”

There is no indication in the text of Directive 98/44/EC that would require a change in this legal interpretation. On the contrary, Article 2 (b) of the Directive affirms the interpretation in the G1/98 decision:

“microbiological process` means any process involving or performed upon or resulting in microbiological material.”

Thus again, Article 4 of EU Directive 98/44 EC cannot be interpreted in such a way that 'absolute product protection' must be issued to cover plants and animals.

Further, Article 3.2 of EU Directive 98/44/ EC (and Rule 27 (a) of the EPC) reads

“Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”

Since the process of breeding plants or animals can hardly be considered to be 'isolating' biological material, Article 3.2 cannot be applied to inventions concerning plants and animals. If, on the other hand, biological material (plants or animals) is produced by a “*technical process*”, the patent covering the process would also cover the plants and animals derived thereof, even if the characteristics already existed in nature. However, Article 3.2 does not request the extension of patent protection to plants and animals with the same characteristics that are derived by non-technical (*essentially biological*) processes.

Consequently, there is no need to issue 'absolute product protection' for inventions concerning plant and animal breeding. This interpretation of the provisions of EU Directive 98/44 is supported by decision C-428/08 of the EU Court of Justice, which generally restricted product protection in regard to biotechnological inventions.

In addition, if 'absolute product protection' is not issued for inventions that interfere with the prohibitions of Article 53(b), this does not call into question product protection in other areas. Such a provision would solely be justified by the necessity to make effective the prohibitions of Article 53 (b).

As a result, only process claims that are clearly based on technical processes should be granted in relation to inventions that concern plants or animals.

b) Exclusion of plant and animal varieties

Article 53(b) also excludes plant varieties. However, in the past this exclusion has often been circumvented by clever wording of the claims, even if the invention as described in the patent application fell under exclusion.

In its G2/06 decision (the so-called WARF-Decision), the EPO chose to apply a so-called 'whole content approach' in the examination of patent applications that – because of ethical concerns - might fall under the prohibitions of Article 53(a). The application of the 'whole content approach' in regard to Article 53(a) was confirmed by the EUCJ in its decision C-34/10.

The 'whole content approach' is meant to prevent the circumvention of prohibitions in patent law by inventive drafting of the claims in patent applications. Therefore, it requests that technically unavoidable pre-process steps and technically unavoidable post-process steps and/or unavoidable post-process uses of the products shall constitute part of the invention, even if they are not explicitly disclosed in the specification and/or the claims of a patent application.

To make sure that none of the prohibitions in Art. 53, EPC can be circumvented by clever, duplicitous drafting of the claims in patent applications, the whole content approach should also be applied to exclusions under Article 53(b). This is in accordance with a resolution passed by the EU Parliament in 2012 (“European Parliament resolution of 10 May 2012 on the patenting of essentially biological processes”). Further legal arguments on the whole content approach can be taken from Dolder, “Die Anwendung von Patentierungsausschlüssen nach dem whole content approach”, Mitteilungen der Deutschen Patentanwälte, Heft 1/2017.

7. Summary: Tabled overview of suggested changes to the text of the Implementation Regulation

The following table summarises the legal analysis and translates the most relevant findings into suggestions for changes to the Implementation Regulation of the EPC.

Original text	Proposed additional text	Comments
Chapter V		
Biotechnological inventions		
Rule 26 General and definitions		
(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.		
	Methods concerning crossing, or selection, or propagation, or processes to introduce or modify a trait at random are regarded as essentially biological. Such processes are still	It can be inferred from the explanatory notice published by the EU Commission that patentable inventions as described in Article 4 of Directive 98/44 solely concern methods of genetic engineering. Therefore, methods and

Original text	Proposed additional text	Comments
	<p>considered essentially biological even if they contain, as a further step or as part of any of the steps of breeding, a step of a technical nature which serves to enable or assist the performance of the breeding process.</p> <p>Only if a material intentionally inserted from outside into the cell introduces a trait into the genome or modifies a trait in the genome of the plant or animal produced, so that the introduction or modification of that trait is targeted and not derived at random, then the process is not considered as essentially biological.</p> <p>Further, if plants or animals derived from non-essentially biological processes are used in breeding, the overall process is not regarded as essentially biological.</p>	<p>materials relevant for conventional breeding have to be excluded as they are “essentially biological processes”.</p>
(6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material.		
	Breeding of plants and animals is not regarded as microbiological process.	To avoid legal uncertainty.
Rule 27		
Patentable biotechnological inventions		
Biotechnological inventions shall also be patentable if they concern:		
(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;		

Original text	Proposed additional text	Comments
	Breeding of plants and animals is not regarded as isolation of biological material from its natural environment.	To avoid legal uncertainty.
(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;		
(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.		
	Breeding of plants and animals is not regarded as microbiological process.	To avoid legal uncertainty.
Rule 28		
Exceptions to patentability		
Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:	Rule 28. 1	
a b c d		
	Rule 28.2 (or Rule 29, new) Under Article 53(b), the following rules apply:	
	All products such as plants/animals and plant/animal parts and genetic information that are used in or obtained by means of essentially biological processes are excluded from patentability.	This provision is mostly derived from the explanatory notice of the EU Commission.
	Patentable plant- and animal-related inventions can only be covered by process claims. In addition, the wording of the process claims has to be defined by the specific technical methods as described in the patent.	This provision is necessary to render the specific prohibitions effective. If absolute product protection is issued to cover plants and animals, the scope of patents granted covering plants and animals derived from methods of genetic engineering

Original text	Proposed additional text	Comments
		<p>could cover those derived from essentially biological processes with same or similar characteristics.</p> <p>The EU Directive does not require absolute product protection to be issued for plants and animals.</p>
	<p>In regard to the exceptions of article 53(b), the whole content approach applies as developed in G2/06.</p>	<p>This is necessary to prevent applicants from escaping the prohibitions by cleverly wording the claims.</p>