



No patents on broccoli, barley and beer!

European patent law must be changed to safeguard the wider public interest

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no patents on seeds

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Annex 1

Patents on plants and animals: The legal debate

In Europe, patenting plants and animals became a major phenomenon in the 1980s and 1990s as the first genetically engineered organisms were created. It has been a highly controversial issue ever since.

In essence, the legal framework of the European patent law, the so-called European Patent Convention (EPC), excludes plants and animals from patentability. As Article 53(b) reads, no patents on plant or animal varieties can be granted:

“European patents shall not be granted in respect of:

(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.”

However, although the European Patent Office has granted thousands of patents on the basis of these legal provisions in recent years, it has very often disregarded and undermined the prohibitions. In the following sections, we resume the discussion on the interpretation of Article 53(b) and set out some recommendations on how to strengthen the relevant prohibitions.

1. “Essentially biological processes” for breeding

The EPO is not part of the EU (see Annex 2). However, for the interpretation of Article 53(b) of the EPC and its exclusion of “essentially biological” breeding from patentability, it makes use of a Patent Directive of the EU (“Legal Protection of Biotechnological Inventions” 98/44/EC). Large parts of the text of this Directive were introduced into the Implementing Regulations of the European Patent Convention.

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.”

This wording led to several legal problems. First, it was difficult to define the meaning of an “essentially biological process”. Secondly, there was lack of legal clarity whether the plants and animals derived from such processes should be patentable.

In 2010, the EPO Enlarged Board of Appeal (EBA), which is the highest legal instance at the EPO, gave an interpretation of “essentially biological processes” used for breeding plants and animals. The decisions are in the G2/07 in regard to the patent on the broccoli (EP 1069819) and the G1/08 (EP 1211926) referral of the patent on tomatoes. Both patents are based on conventional plant breeding and cover the process for breeding as well as the plants, the seeds and the fruits (the food).

In its decisions G2/07 and G1/08, 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.”

However, the decision raises several questions since the definition is not 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*”. This wording is narrowing the scope of the exclusion substantially.

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 not only 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*”. The EPO also applies this reasoning to plants and animals that inherit traits based on random mutations and are used in conventional breeding and – from the perspective of patent law – should be regarded as *essentially biological*.

In 2015, the Enlarged Board of Appeal of the EPO again decided upon patentability of conventional breeding. The so-called ‘broccoli and tomato decision II’ (decision G01/12 and G02/13) gave an extremely biased interpretation of current patent law: While processes for conventional breeding cannot be patented, plants and animals stemming from these processes are patentable.

This interpretation of European patent law is not only contradictory in itself, but it also undermines the prohibitions in European patent law. Many experts in the field observed that it would not make any sense to exclude just the processes for breeding while allowing patents on plants and animals. Consequently, the prohibition of Article 53(b) could no longer be applied in a meaningful way.

In response to these discussions, the EU Commission issued an Explanatory Notice on the interpretation of Article 4 of EU Directive 98/44/EC.⁸ 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.”

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.”

⁸ [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01))

This explanatory statement was in clear contradiction to the decisions of the Enlarged Board of Appeal at the EPO (G2/12 and G2/13), and also at least partially diverges from the one given by the EPO in G2/07 and G1/08. In general, the definition provided by the EU Commission follows the generally accepted 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.

From the perspective of patent law – which is not directly linked to the regulation of genetically engineered organisms – it can be presumed that decisions G2/07 and G1/08 of the Enlarged Board of Appeal should be interpreted 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 issued by the EBA (G2/07 and G1/08). It is derived from the context and the history of the EU Directive.

The statement of the EU Commission followed after two resolutions were passed by the EU Parliament in 2012⁹ and 2015¹⁰. In 2017, the statement was adopted by the Member States of the EU.¹¹ In its decision taken in February 2017, activities are requested in regard to a change in the Implementing Regulations of the EPC. The decision

“urges Member States, in their capacity as members of the European Patent Organisation, to advocate that the practice of the European Patent Organisation is aligned with these conclusions.”

Consequently, there was now some urgency that the EPO should adapt its legal practice in accordance with the interpretation presented by EU institutions. However, in the decision taken by the Administrative Council in June 2017¹², the EPO failed to fully adopt the EU Commission notice. In essence, the changes to the Implementing Regulations to the EPC adopted by the Administrative Council are:

1. It followed the Notice of the EU Commission to the extent that products derived from “essentially biological processes” should not be patented; but
2. It diverged from the Notice of the EU Commission in the definition of an “essentially biological process”: The EPO still considers only plants and animals derived from crossing and selection as not-patentable, while treating processes that concern the selection without crossing or random mutations as patentable inventions.

In conclusion, the EPO continues to grant patents on plants derived from random mutations.

As explained, the selection of genetic characteristics that are not introduced by technical intervention,

⁹ www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN

¹⁰ www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2015-0473&language=EN&ring=P8-RC-2015-1394

¹¹ www.consilium.europa.eu/register/en/content/out/?&typ=ENTRY&i=ADV&DOC_ID=ST-5808-2017-INIT

¹² www.epo.org/news-issues/news/2017/20170629.html

but derived from a broad range of variability, is one of the most basic principle used in conventional breeding. Therefore, if patents are granted on such genetic characteristics these patents will affect a broad range of conventional breeding on many levels.

In November 2017, the EPO published new Examination Guidelines, taking into account the June 2017 changes to the Implementing Regulations to the EPC with regard to patentability of “essentially biological” breeding. These guidelines clearly show that the EPO still considers conventional breeding to be being patentable. Methods for selection of plants and animals, the usage of genetic markers and random mutations are all regarded as patentable. No distinction is made between technical interventions (such as gene editing using “CRISPR/Cas”) and random mutations triggered by sunlight (“UV mutagenesis”).

Box: From the examination guidelines of the EPO, November 2017

Typical formulations of subject-matter not excluded from patentability under Art. 53(b):

- Method for selecting animals having phenotype Y by screening for the presence of a marker having the sequence shown in SEQ ID NO: 1.
- Use of the nucleic acid of SEQ ID NO: 1 to select a plant having trait X.
- A mutant of a plant carrying a heritable exchange in a nucleotide sequence effected by technical means, e.g. UV mutagenesis or CRISPR/Cas.

2. Plant and animal varieties

Article 53(b) of the EPC also excludes plant and animal varieties from patentability. 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 the exclusion.

The EU Directive 98/44/EC is also decisive for current interpretation. Before the Directive came into force, decision in case T356/93 decided in 1995 by the Technical Board of the EPO, meant that patents on plants and animals could not be granted because such patents would inevitably extend to plant and animal varieties. This was seen as a contradiction to the wording of Article 53(b) EPC.

This interpretation of Article 53(b) was not changed until the Directive 98/44/EC was adopted. The Directive became part of the Implementing Regulations of the EPC in June 1999, at which point the EPO resumed granting patents on genetically engineered plants. The basis for these patents was mostly derived from Article 4.2 of the EU Directive 98/44/EC:

“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.”

In parallel, the Enlarged Board of Appeal at the EPO was also preparing the G 1/98 decision, which was published some months after the Directive was incorporated into the Implementing Regulations. In its decision, the Enlarged Board of Appeal more or less applied the logic behind Article 4.2 EU Directive 98/44/EC.

A diagram presented by a representative of the EPO at a conference in 2011, shows the effect that this new interpretation had (see figure 7): It shows that, for example, although a patent cannot be granted on a specific variety of apples with a higher content of vitamins, a claim can be made for all plants possessing the patented characteristic, e.g. all apples with a higher content of vitamins. This means that a patent can be granted on plants with a higher content of vitamins that will cover all plant varieties that are of specific interest. As a consequence, the prohibition of patents on plant and animal varieties is no longer of major relevance in EPO decision-making. And – as the diagram shows – the EPO in essence gave industry an option to circumvent the regulations.

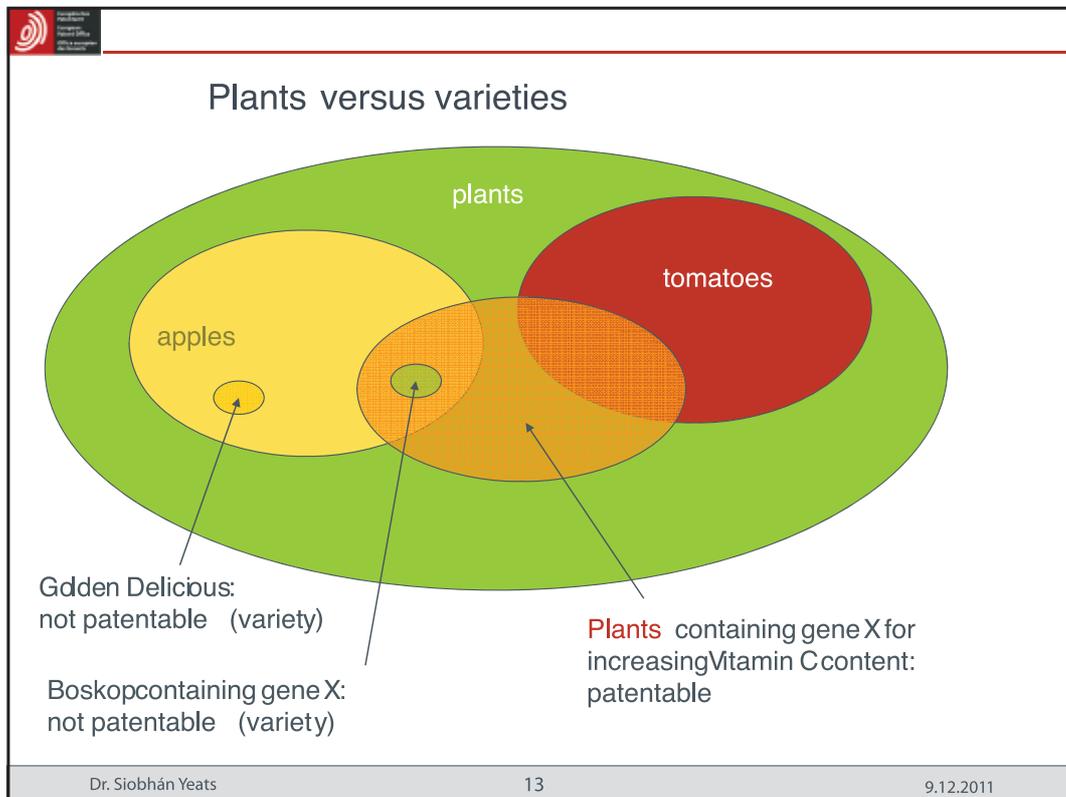


Figure 7: This slide shows how the European Patent Office currently interprets the prohibition of patents on plant varieties. While it is not possible to patent a defined variety of apple with a higher content of vitamin C, it is possible to grant a general claim on plants with an elevated content of vitamins as an invention. Consequently, all apple varieties of interest are included in the scope of the patent and become de facto patentable. (Source: EPO, 2011)

This legal practice was developed in the context of genetically engineered plants and expanded to conventional breeding by the EPO. However, the criteria applied in *G1/98* to define what is patentable were not meant to be applied to conventional breeding: Even according to decision *G1/98*, plant varieties with characteristics that are based on a genotype (a specific combination of genetic conditions) were still regarded as not patentable. Only if a plant could not be defined by its whole genome, but by a characteristic linked to specific defined and inserted DNA sequence i.e. the herbicide resistance, it was not excluded from patentability.

But many of the relevant plant characteristics described in patents on plants derived from conventional breeding are not based on a single DNA sequence, but upon a combination of genetic conditions. Thus, the characteristics of these plants can be more accurately described as stemming from “a given genotype”, but not as being “defined by single DNA sequence”.

In general, the criterion “if the technical feasibility of the invention is not confined to a particular plant or animal variety” (Article 4. 2 of the Directive 98/44/EC) can hardly be applied in the field of conventional breeding. As has been explained, it can be assumed that “technical feasibility” is directed at processes for genetic engineering which enable the transfer of DNA sequences beyond the boundaries of species. In this context, the criterion has a specific technical meaning.

But in conventional breeding, any plant characteristics can be transmitted to any other varieties within the same species, just by further breeding. As a result the criterion as given in Article 4.2. and applied by the EPO does not have a specific technical meaning and does not provide any legal clarity in the context of conventional breeding.

In summary, if the provisions of Article 53(b) 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 show characteristics that are based on a genotype and not only single DNA sequences
- 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.

It can be concluded that in the context of conventional breeding the overlap between plant variety protection and patent protection is much stronger, and raises new legal and urgent questions in comparison to patents granted in the field of genetic engineering.

However, the EPO Examination Guidelines from 2017 explicitly allow the patentability of plant varieties to the area of conventional breeding.

Box: From the examination guidelines of the EPO, November 2017

A patent is not to be granted if the claimed subject-matter is directed to a specific plant variety or specific plant varieties. The method for the plant’s production, be it by recombinant gene technology or by a classical plant breeding process, is irrelevant for considering this issue (...).

Table 4: Overview of some decisions made by the Boards of Appeal at the EPO concerning patents on plants and animals and the examination guidelines from EPO (2017)

| Number decision / source | Question / topic | Position of the EPO |
|----------------------------------|---|--|
| T356/93 | Can patents be granted on genetically engineered plants or are these patents in conflict with prohibition of patents on plant varieties (Art. 53(b) EPC)? | No, these patents cannot be granted. |
| G 1/98 | Can patents be granted on genetically engineered plants or are these patents in conflict with prohibition of patents on plant varieties (Art. 53(b) EPC)? | Yes, such patents can be granted. |
| G2/07 and G1/08 | What does it mean that patents on essentially biological processes for breeding plants and animals are not allowed? | Processes based on sexual crossing of whole genomes and further selection cannot be patented. |
| G2/12 and G2/13 | Can products such as seeds, plants and fruits derived from essentially biological processes be patented? | Products derived from processes based on sexual crossing of whole genomes and further selection can be patented. |
| Examination guidelines, EPO 2017 | Definition of essentially biological processes | Processes for selection of plants or random mutations are considered as patentable. |
| Examination guidelines, EPO 2017 | Does the scope of patents granted on plant characteristics also extend to plant varieties if these are derived from conventional breeding? | Yes. |

3. Can patents on plants and animals be prohibited in general?

As mentioned, in regard to plants and animals, Article 53(b) of the EPC requests that:

“European patents shall not be granted in respect of:

(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.”

For many years, especially before genetic engineering came into play, patent experts interpreted this provision as meaning that no patents on plants and animals could be granted. The EPO only rarely granted patents on plants prior to the introduction of genetic engineering.

With the introduction of genetic engineering, the EU introduced its Patent Directive 98/44/EC. It requests that

“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.”

However, the Directive does not explicitly state that patents should be granted on plants and animals as such. Rather, the patents on plants and animals could be restricted to technical processes. In any case,

the Directive can only be used as a tool to interpret the text of the EPC. Changes in the text of the EPC can only be introduced by the 38 Contracting States of the EPC (the EU Member States plus 9 others, such as Turkey and Switzerland). Thus, it is decisive, if the EPC requests patents on plants and animals to be granted. This question can simply be answered with ‘No’.

There is no indication in the wording of the EPC 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 legislation. For example in Switzerland, in 1976 when the 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.

The legal situation only changed after methods of genetic engineering were introduced. In 1998, an EU Patent Directive was adopted (98/44/EC). The text of the EU Directive was then integrated into the Implementing Regulations of the EPC.

However, taking a look at the historical context, the interpretation of the EPC should be much more cautious in regard to patents on plants and animals than is currently the case. Even in the light of the text of the EU Directive, there are many possibilities to restrict patents in this field to technical applications; and to no longer grant product claims on plants and animals in future.

This will be explored in the following chapters.

4. The way forward: Patenting technical applications, not turning living beings into patentable ‘products’

The granting of European patents has to be restricted in a way that avoids any overlap between what can be patented and what is excluded from patentability under Article 53(b) of the European Patent Convention (and Article 4 of the European Patent Directive). This includes issues related to plant and animal varieties as well as plants, animals or products which could be produced by conventional breeding (essentially biological processes) as well as by technical processes using methods of genetic engineering, including gene editing.

So far, EPO legal practice results in legal absurdities that render the prohibitions of Article 53(b) ineffective. In fact, the broader the scope of the patent application concerning plants or animals, the more likely it is that the EPO will grant the patent: If all plants with specific characteristics and all processes for breeding (that might be applied in theory) are claimed, there is a high likelihood that the patent will be granted. The applicant only has to make sure that specific varieties or specific processes for “essentially biological” breeding are not claimed explicitly to be in accordance with the wording of the law.

Consequently, the scope of patents granted on plants (or animals) derived from technical processes may encompass plants (or animals) sharing the same characteristics obtained by “essentially biological processes”. Even though these are not deemed patentable, they still may fall under the scope of a patent. This is a general problem that was also described in a report prepared on behalf of the German government in 2011 (Herdegen & Feindt, 2011).

In general, the scope of patents is regulated by national laws. For example in German patent law, there are provisions to reduce the scope of patents in the medical area. Further, Article 10 in French Biodiversity Law (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 limit the scope of patents by the wording of the claims as granted. In this context, the difference between claims on the processes and claims on the products are crucial: If a patent is granted on the process only, the scope of the patent is reduced to the product derived from that specific process. On the other hand, if patents are granted on the product, all products with the relevant characteristics are within the scope of the patents, no matter how they are produced. Thus, patents granted on products provide what is called ‘absolute product protection’.

In the context of Article 53(b) absolute product protection is highly problematic: If ‘absolute product protection’ is provided for plants 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 process used to produce plants or animals. Consequently, if ‘process claims’ are granted on methods of genetic engineering, then plants and animals obtained by these methods may fall within the scope of the patent, including 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.

The EU Directive and the EPC do not request ‘absolute product protection’ for inventions concerning plants and animals. Especially 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.

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.

Consequently, there is no need to issue ‘absolute product protection’ for inventions concerning plant and animal breeding. Limiting the scope of product protection in regard to Article 53(b) is in line with the Decision of the Court of Justice of the EU C-428/08 on Monsanto as well as with national patent legislation on nucleic acid-related inventions in Germany, France, Luxembourg, Italy and Poland.¹³

13 See report of the Expert Group on “The development and implications of patent law in the field of biotechnology and genetic engineering”, published by the EU Commission (E02973), <http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/>

It is also in line with the “European Parliament resolution of 17 December 2015 on patents and plant breeders’ rights” which calls for introduction of full breeders’ exemption into patent law. Indeed, the limited scope of protection would provide legal clarity and certainty for conventional breeders by effectively replicating the breeders exemption in plant variety protection system: As long as conventional breeders are not using methods for genetic engineering, gene editing or methods that enable a targeted introduction of a trait into plants or animals, or material derived thereof in their breeding work, they do not have to worry about the patent system but have sufficient freedom to operate.

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.

Annex 2

The European Patent Office and the European Patent Convention

The European Patent Office (EPO) is part of the European Patent Organisation (EPOrg), which was set up as an intergovernmental organisation on the basis of the European Patent Convention (EPC), signed in 1973¹⁴.

In general, the interpretation of the EPC and the content of the Implementing Regulations is governed by the Administrative Council of the EPO which represents the Contracting States of the EPC. The European Patent Organisation currently has 38 Contracting States, comprising all the member states of the European Union together with Albania, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey.

The two main institutions within the European Patent Organisation (EPOrg) are the European Patent Office (EPO) and the Administrative Council. While the EPO examines and grants patents filed by the applicants, the Administrative Council, made up of representatives of the contracting states, is a supervisory body responsible for overseeing the work of the EPO. The Administrative Council nominates the president of the EPO and can decide on the interpretation of the EPC and its so-called Implementing Regulations.

The EPOrg is not part of the European Union (EU), which means that EPO decisions are not under the jurisdiction of the European Court of Justice. Instead, the EPO has three levels of decision-making of its own on granting patents:

- The Examining / Opposition Divisions responsible for granting patents and oppositions in the first instance.
- The Technical Board of Appeal responsible for cases that are not decided in the first instance.
- The Enlarged Board of Appeal which is the highest legal decision making body at the EPO: the Enlarged Board of Appeal does not decide on the granting of particular patents, but is responsible for legal matters of relevance and for examination and granting of patents in general.

¹⁴ <http://www.epo.org/about-us/organisation/foundation.html>