no patents on seeds

Patent applications on plants derived from conventional breeding 2016

New industry strategy for acquiring patents on plants derived from conventional breeding

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Content

1. Overview and conclusions

This overview was compiled to present in-depth information on current patent applications in plant breeding. The research for this project was carried out amid ongoing controversy regarding patents on plants and animals. Currently, many civil society organisations, traditional breeders and farmers' organisations are demanding a stop to patents on plants and animals as well as on breeding material used in, or derived from, conventional breeding. These demands are supported by relevant EU institutions i.e. the EU Parliament, the EU Commission and the EU Council. At the same time, the EU is urging the European Patent Office (EPO) to move towards adopting a new legally binding interpretation of the European Patent Convention (EPC).

1.1 The legal provisions

The most relevant legal provision in this context is Article 53(b) of the EU Patent Convention (EPC), which excludes patents on:

"essentially biological processes for the production of plants or animals."

How can "essentially biological" breeding be defined and what has to be excluded in order to have a meaningful and effective prohibition that provides sufficient clarity and certainty? At present, the EU is demanding that inventions concerning genetically engineered plants can still be patented in future. However, methods used in conventional plant breeding need to be excluded.

In 2010, the European Patent Office (EPO) defined the "essentially biological" breeding of plants and animals as *"crossing (…) and of subsequently selecting plants"*. Consequently, such processes cannot be granted under Article 53(b) of the European Patent Convention (EPC).

From the perspective of patent law, this definition is very narrow. For example, selection without crossing (such as screening for specific genetic conditions) or propagation without sexual crossing (such as selfing) are not excluded.

Quite recently, the institutions of the EU made it clear that they considered that not only the processes, but also the plants and animals derived from essentially biological processes were non-patentable. At present, the EU is urging the European Patent Office (EPO) to adopt a new legally binding interpretation of the European Patent Convention (EPC) to exclude from patentability not only processes for breeding, but also plants and animals derived from conventional breeding. Many observers expect a decision to be taken in 2017. Thus, it is essential to find a political solution that provides sufficient legal clarity and certainty within the coming weeks and months.

1.2 New strategies in patent applications

In previous years, patents on conventional breeding, including the precedent cases of broccoli and tomatoes, were mostly based on the process of sexual crossing and selection. But as this research shows, there has been a change in the strategy of how these patent applications are worded: Crossing of plants is no longer claimed as decisive a starting point for breeding in the patent applications.

Technology in conventional breeding has not changed since 2010, and crossing and selection are still the basis of plant breeding in this area. However, these steps have mostly disappeared from the wording of the most recent patent applications. This is an important finding since the processes of crossing and selection are currently highly relevant for the EPO definition of what is excluded under Article 53(b) and they cannot be patented as "essentially biological". But, as this research shows, it is quite easy for industry to escape this definition by wording their applications in a different way.

At the present time, companies and their patent attorneys are following a simple, twofold strategy in their patent applications:

(1) The first step is to direct the claim to the selection of genetic variations or other breeding characteristics, without referring to any crossing. In some cases, the genetic information is additionally claimed as being "isolated" to render it patentable and give the overall process a technical profile.

(2) The second step is to describe the way in which the genetic variations traits or other breeding characteristics are used in the plant breeding process - using complex terminology to insinuate a technical approach. For example, by using the term “introgression” - this simply means that a genetic trait was moved into the genome of another plant. This term could be used to describe what happens in a wide range of breeding processes, such as crossing and selection, random mutagenesis, genome editing or transgenesis.

Using this twofold strategy, the patent, if granted, would cover all plants and subsequent generations and products that inherit or show the characteristics as described, regardless of which breeding process they were obtained from – even if derived from essentially biological processes.

1.3 Current EPO practice

Analyses of current EPO examination practice in this report show that the strategies to escape the prohibitions in Article 53(b) are not only being accepted but are being actively promoted by the EPO: The EPO even advises the companies on how to change the wording of their claims (see below).

The patents granted to Carlsberg and Heineken exemplify the new types of patents being granted by the EPO. In 2006, Carlsberg and Heineken received two patents on barley that inherits random mutations. They were subsequently granted a third patent which covered the further crossing of the barley plants. The patents cover the barley, the process and the derivative beverages. The reason given for granting these patents is that the random mutations were not derived from crossing and selection. In 2016, up to 60 percent of patents granted on conventional breeding by the EPO were based on random mutations.

Therefore, it is hardly surprising that the most recent patent applications follow this legal EPO practice. A great many patent applications similar to those granted to Carlsberg and Heineken were filed in 2016, some of them were based on random mutations and some were based on existing genetic variants. For example, patents such as those granted on barley have now been filed on wheat and derivative food. Other patent applications filed in 2016 were for tomatoes, peppers and lettuce. All the claims in these applications are worded in a similar way.

1.4 How can the increasing monopolisation of seed and food production be stopped?

The logic behind these patents is to monopolise plant breeding and food production. In many cases, there are several ways of developing plants with desired traits. Therefore, companies are attempting to acquire broad-based patents that cover all relevant processes, regardless of whether they are essentially biological or not. One key strategy is to patent genetic or phenotypical characteristics (called traits) that can be transferred to many other varieties. A single patent on a trait, such as resistance to plant pests, can be extended to hundreds of varieties. Finally, the patents not only cover the seeds but also the plants, the harvest and processed foods.

Political decision-makers need to take action to defend the interests of the general public, traditional breeders, farmers, food producers and consumers.

As yet, none of these interests are represented at the EPO.

Conversely, the EPO has strong vested interests in granting such patents since its budget is entirely

based on fees paid by patent applicants. Furthermore, it should not be overlooked that both the patent attorney lobby group, the Institute of Professional Representatives at the European Patent Office (epi), and the lobby group for companies (BUSINESSEUROPE) are represented as permanent observers in the executive bodies of the EPO.

Now, however, the EU governments can act jointly to achieve adequate solutions since they have a majority amongst the 38 contracting states of the EPC represented in the Administrative Council of the EPO. If a two third majority countries is achieved, the rules of interpretation of the EPC ("Implementing Regulations") can be changed via the Administrative Council.

To make the prohibitions of Article 53(b) effective, governments need to insist on the following rules of interpretation:

- All methods used in conventional plant breeding, such as selecting processes and use of random mutations, must be excluded.
- All plants and animals, as well as breeding material and genetic conditions used in, or derived from, conventional breeding have to be excluded.
- The scope of patents granted on methods of genetic engineering has to be restricted in a way that avoids any overlap with the prohibitions in Article 53(b).

No Patents on Seeds! has drawn up a draft text that can be used as a guideline on how effective rules for interpretation can be integrated into the Implementing Regulations of the EPC.

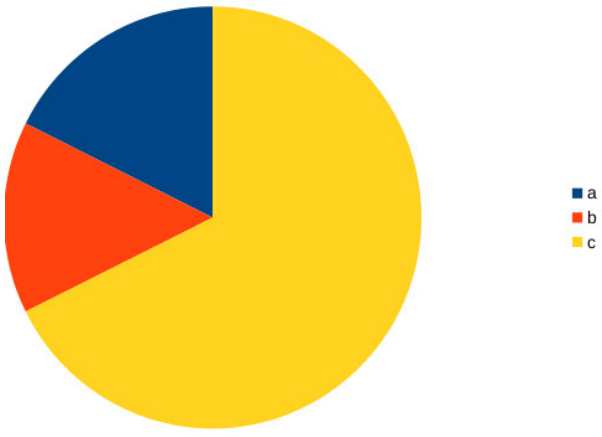
2. Overview of patent applications

This overview is based on research carried out into patent applications filed mostly at the World Intellectual Property Organisation (WIPO) from January to December 2016. The research is based on searches of the relevant databases with relevant International Classifications, the names of companies and on the analysis of the content of several hundred patent applications.

2.1 How many patents were there on conventional breeding?

The research showed that there were around 60 patent applications on conventional breeding. . Around a further 50 patents were filed for a combination of conventional breeding and methods of genetic engineering. In addition, around 230 patent applications were found on genetic engineering only (such as using processes to insert nucleic acids or methods of genome editing). Therefore, around 30 percent of all patent applications on plants concern conventional breeding (see Figure 1).

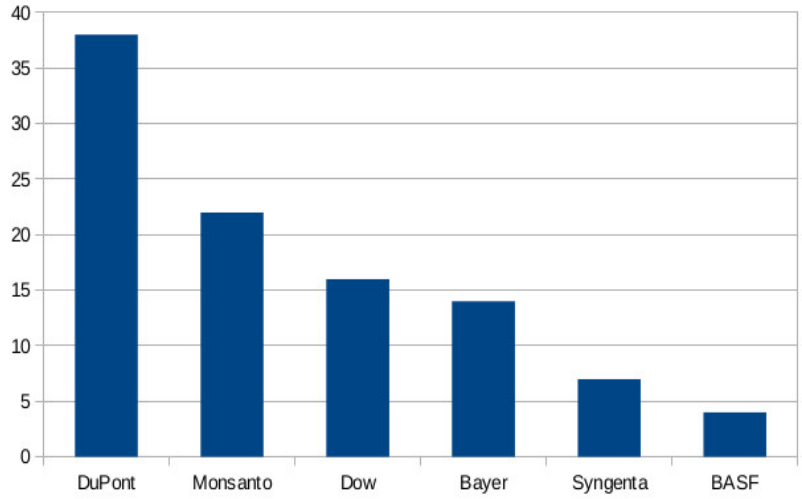
Figure 1: Patents on
(a) wholly or
(b) partially conventional plant breeding and
(c) patents solely on genetic engineering (overall number of patent applications: 340).



2.2 Who is filing these patents?

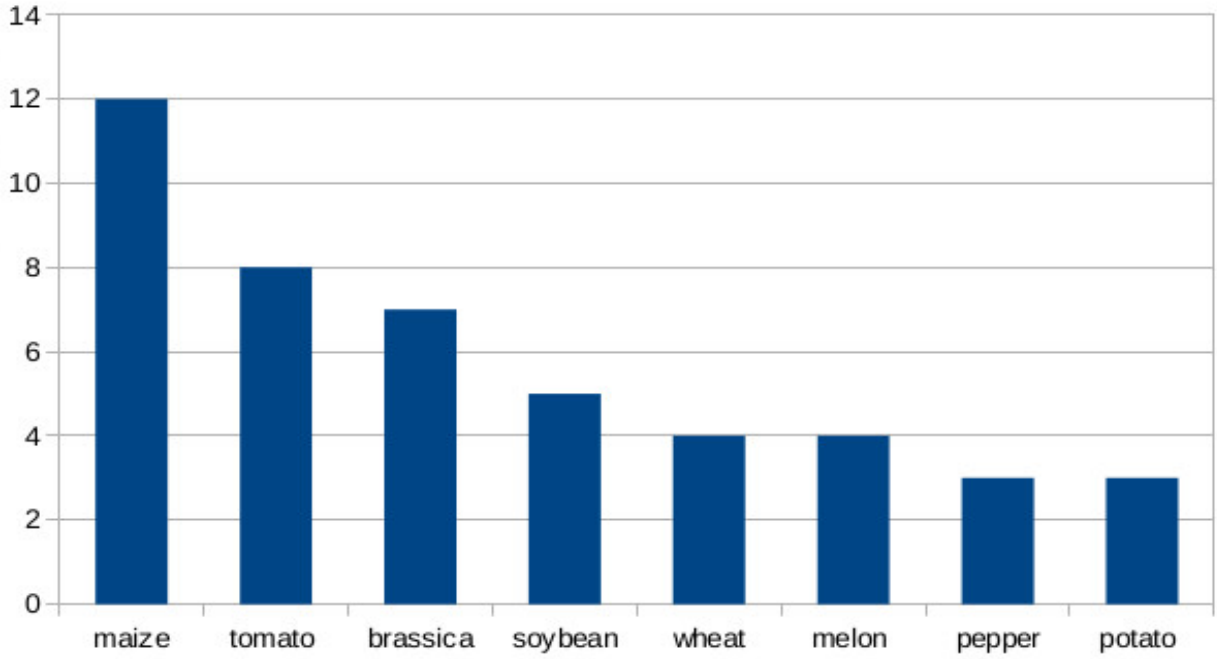
The patent applications are being filed by both large and small companies as well as universities. The companies who filed the most patent applications in this area were Dupont, Monsanto, Dow, Bayer and Syngenta (see Figure 2).

Figure 2: Patent applications on plants per company (overall number of patent applications: 340).



2.3 What is being claimed as an 'invention'?

Some of the plants species specifically named in the patent applications are maize and tomatoes



(see Figure 3). However, many patent applications are not refined to a particular species.

Figure 3: Some of the most frequently named species in the patent applications (overall number of patent applications: 340)

Many patents not only cover the seeds but also the plants, the harvest and food derived thereof. For example, the patents claim vegetables such as tomatoes, lettuce, cucumber and fruits, such as melons. Processed products such as oil, vegetable or milled wheat are also amongst the 'inventions' being claimed. As a result, these patents will not only affect breeders and farmers, but also food producers and consumers (see examples below).

2.4 Will further patents on conventional breeding be granted?

Special investigations were carried out to analyse the wording and the content of patent applications in the field of conventional breeding; patent applications targeting plants and not only processes were analysed in more detail. In most of these applications, the claims are worded in a specific way to escape the prohibitions in Article 53(b):

- The claims are mostly based on a description of desired genetic elements, no matter how they were introduced into the plants.
- Some patents also claim phenotypical plant characteristics (such as colour or size of the fruits).
- Crossing and subsequent selection are not mentioned as the decisive starting point of the 'invention'; more general terms such as “introgression” are used instead.
- In many patents there is intended confusion about the method that was used, or which is the most preferable method to introduce the traits into the plants that are needed for cultivation. The goal is to give the impression of a higher technical profile than actually needed to produce relevant plants.
- The scope of the patents is not restricted to specific techniques but concerns all plants and breeding material with the characteristics as claimed.

As current case law at the EPO shows, these patterns in the wording of the patents are not driven by technology or processes, but mostly by legal reasoning aiming to avoid the prohibitions in Article 53(b). The way in which the EPO currently deals with patent applications can be clearly seen by looking at the patents granted to Carlsberg and Heineken EP2384110, EP2373154 and EP2575433 (on barley derived random mutations and further crossings), or by looking into EPO examination reports of pending cases, such as EP 2134870 (selection of soybeans) or EP 2571347 (cucumber derived from random mutagenesis).

Consequently, the provisions of Article 53(b), EPC will not be effective in the assessment of these patent applications.

3. Some examples

This section contains some examples of typical patent applications on conventional breeding. In previous years, a great many applications were filed, such as those on broccoli (EP1069819) and tomatoes (EP1211926), with descriptions based on crossing and selection - but this is hardly the case anymore. Instead, in most cases, the patent applications start with the selection of the plants with the desired genetic traits and / or breeding characteristics and then simply claim the relevant plants, the seeds, and the harvest.

In most cases the patent claims now are directed to:

- The selection of desired genetic traits found in nature or stemming from random mutations

- Plant characteristics such as the quality of fruits or grains or resistance to pests
- All plants inheriting inhering these traits.
- All relevant food products, such as fruits, processed meal or oil.

To provide an overview, the examples were grouped into the following categories, with several of the patents overlapping with more than one category:

- Screening of genetic variations in existing plant populations (domesticated and/ or wild populations)
- Usage of random mutations
- Masking essentially biological processes
- Propagation without sexual crossing

3.1 Screening of existing plant populations

The example given in this category is a patent application filed on oilseed rape bred to reduce losses of kernels during harvest.

Application Number: WO2016011146
Species: oilseed rape
Company: DuPont/ Pioneer
Title: QTLs associated with and methods for identifying shatter resistance in canola

Content:
The background of the patent are losses in the harvest of oilseed rape. During the process of harvesting, the plants can spontaneously drop their seeds / kernels needed for oil production. This effect is known as pod shatter. Pioneer screened several populations to identify genetic traits in the plants that can reduce pod shatter.

Pioneer is claiming these genetic traits as their invention. Further, all plants inheriting the described genetic traits as well as their offspring are claimed as inventions. Pioneer claims they isolated and synthesized the relevant genetic information and that the DNA might be used in methods of genetic engineering. In effect, if the patent were to be granted it would cover all plants and subsequent generations and products that inherit or show the traits as described, including if they were derived from essentially biological processes.

Similar patent applications:

- Dupont/Pioneer on maize (WO2016003577) and soybeans (WO2016057459),
- DowAgroSciences on maize (WO2016064597), oilseed rape (WO2016100883) and soybean (WO2016196787),
- Monsanto on oilseed rape (WO2016176358) and maize (WO2016176286),

3.2 Random mutations

The example given in this category is a patent application filed on wheat with a genetic trait to prolong the shelf life of the derivative food products.

Application Number: WO2016205644
Species: Wheat
Company: Arcadia Biosciences, US

Title: Wheat with reduced lipoxygenase activity
Content:
Naturally occurring plant enzymes known as lipoxygenase can reduce the shelf life of food derived from these plants. US Company Arcadia, which also collaborates with Dow AgroSciences, identified mutations and variations in the DNA of wheat and its related species that cause a reduction in lipoxygenase activity and can therefore prolong the shelf life of products such as grains, flours and bread. Some of the mutations were introduced at random; the same or similar genetic variations are likely to already exist in the plant populations.

Arcadia Biosciences claims all relevant mutations and genetic variations in wheat plants and all wheat plants with the relevant characteristics. To mask the claims on essentially biological processes, methods such as the creation of transgenic plants are mentioned and any kind of “human intervention” is emphasised.

However, in effect, if the patent were to be granted it would cover all plants and subsequent generations and products that inherit or show the conditions as described, including if they were derived from essentially biological processes.

Not only the seeds and wheat plants are claimed, but all food products derived thereof, such as flour and bread. The patent application is very similar to the ones granted to Carlsberg and Heineken (EP2384110 and EP2373154): These patents are based on random mutations; all relevant barley plants as well as the process of brewing and all beverages are claimed as 'inventions'.

Similar patent applications:

- Arcadia on wheat (WO2016196489).
- Bayer (and Nunhems) on tomatoes (WO2016202927; WO2016016208) and oilseed rape (WO2016176476)
- Dupont on sorghum, rice and maize (WO2016099918)
- Cargill on oilseed rape (WO2016089677).

3.3 The masking of essentially biological processes

The example given in this category is a patent application filed on tomatoes with resistance to a plant pest (powdery mildew). The resistance was originally found in plants of a tomato species found in Chile and Peru.

Application Number: WO2016191090
Species: Tomato
Company: Seminis / Monsanto
Title: Tomato plants with improved disease resistance

Content:
Seminis describes how the genetic trait in a wild species of tomatoes (*Solanum chilense*) was identified that provides resistance to powdery mildew (*Leveillula taurica*). The genetic trait was transferred to tomato plants used for cultivation by crossing and selection. Marker-assisted selection was used to speed up the process.

The company, which is owned by Monsanto, claims all tomato plants with an “introgression” of the relevant genetic trait. All plants that contain the relevant DNA, are claimed as an invention. To

avoid the prohibitions in Article 53(b), the patent description explains that gene editing might also be used to establish the plants.

Similar patent applications:

- Monsanto / Seminis on tomatoes (WO2016061107) and melon (EP3005862),
- Bayer / Nunhems on cucumber (WO2016177696), tomatoes (WO2016202927) and lettuce (WO2016066748).

3.4 Propagation without sexual crossing

Since the definition of essentially biological methods is based on sexual crossing, all patents that concern methods for propagation with crossing such as selfing or pruning can escape the prohibitions in Article 53(b), EPC.

The example given in this category is a patent application filed on sweet pepper that is propagated by pruning.

Application Number: WO2016142332
Species: *Capsicum*
Company: Nunhems/ Bayer
Title: Pruning method for improved seed production

The pepper plants are propagated by pruning: The branches are cut as they would be for the cultivation of new plants for further breeding. If the patent is granted, all *Capsicum* plants (such as sweet pepper) that are propagated in this way, would become an 'invention' of Nunhems, which is owned by Bayer.

Nunhems claims “a plurality of pruned *Capsicum* plants, no matter which characteristics they may have.

There are other patents filed in this area such as, for example, the one filed by Monsanto / Seminis (WO2016066748), which claims selfing of lettuce plants with specific genetic traits.

4. Some more legal and political background

The text and the rules of interpretation (“*Implementing Regulations*”) of the European Patent Convention (EPC) and the text of the EU Directive “*Legal protections of biotechnological inventions*” (98/44 EC) must both be taken into account for the interpretation of prohibitions in Article 53(b).

4.1 The provisions of the EPO

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 1973[1].

[1]http://www.epo.org/about-us/organisation/foundation.html

In regard to plant and animals, the EPC has a unique exclusion: Article 53(b) 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 European Patent Office (EPO) only rarely granted patents on plants prior to the introduction of genetic engineering.

There is 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. An 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.

The legal situation only changed after methods of genetic engineering were introduced. In 1998, an EU Patent Directive was adopted (Legal Protection of Biotechnological Inventions, 98/44 EC – see below). The text of the EU Directive was integrated into the Implementing Regulations of the EPC, thereby making it a part of rules for the interpretation of the EPC and the basis for several EPO decisions. Based on the text of this Directive, the EPO granted more than 2500 patents on genetically engineered plants and animals.

4.2 The institutions of the European Patent Organisation

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 Administrative Council acts to a limited extent as a legislative body for the EPO, with its statutes giving a degree of political control. The council is made up of the following members and observers who regularly take part in the meetings:

- The contracting states of the EPOrg are represented by two delegates from each country. The representatives are mostly from the national patent offices, or are legally qualified staff members of national authorities. They are bound to the mandates of their governments.

- Other participants in the meetings of the Administrative Council are the President of the EPO, auditors and several EPO staff members. There are some observers from intergovernmental organisations: the European Union (EU), the World Intellectual Property Organization (WIPO), the Office for Harmonization in the Internal Market (OHIM) and the Nordic Patent Institute (NPI).

- In addition, there are two non-governmental organisations at the meetings of the Administrative Council; they take part as observers and have vested interests of their own. These are BUSINESSEUROPE and the Institute of Professional Representatives at the European Patent Office (epi).

  BUSINESSEUROPE is an umbrella organisation for national business federations and industry in 35 countries[2].

  The Institute of Professional Representatives at the European Patent Office (epi) represents the European patent attorneys[3]. There are thousands of registered European Patent Attorneys in Germany as well as in the UK[4]. Patent attorneys, law companies, legal experts and consultants all earn money with patent applications, the granting of and opposition to patents and other legal services. This can be regarded as a highly profitable 'patent industry' in its own right.

While the stakeholders participating at the Administrative Council meetings, such as BUSINESSEUROPE or epi, are heavily directed to the vested interests in obtaining patents, other civil society organisations are not represented at all.

4.3 The EU Patent Directive 98/44

The EU Directive Legal Protection of Biotechnological Inventions (98/44 EC)[5] was adopted by the EU Parliament and EU member states in 1998. The EU Directive 98/44 was adopted in the historical context of the introduction of methods for genetic engineering. In its Article 4, the Directive requests patents are granted on "*inventions which concern plants or animals*", but does not request for patents on plants and animals as such.

Although the EPO is not part of the EU, the Directive became part of the Implementing Regulations of the European Patent Convention in a vote taken by the Administrative Council in 1999. The relevant rules of the Implementing Regulations are Rules 26 to 34.

There are substantial reasons to assume that when adopting Directive 98/44, the legislator wanted to restrict patents on plant-related inventions to those that are derived from genetic engineering. The Directive, in its 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

[2]http://www.businesseurope.eu/content/default.asp?PageID=600
[3]http://www.patentepi.com/en/the-institute/list-of-professional-representatives/
[4]http://www.epo.org/applying/online-services/representatives.html Previous research in 2014 showes around 4000 patent attorneys in Germany and 2000 in UK.
[5]http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044

engineering, but not on methods applied in 'conventional' breeding.

This was also confirmed by an 'Notice' published by the EU Commission in 2016 that was adopted by EU Member States in 2017. In November 2016, the EU Commission specifically drew up an explanatory notice on the interpretation of Article 4 of EU Directive 98/44/EC.[6] 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."*

In its statement, the EU Commission – based on the history and the text of the EU Patent Directive 98/44 – 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."*

It also concurs with a resolution by the EU Parliament adopted in 2012[7]. According to the text of the resolution, the EU Parliament:

> "*4. Calls on the EPO also 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;*"

Therefore, it can be assumed that in plant breeding at least, all conventional breeding methods (such as selection or crossing, usage of random mutations) as well as all products and breeding material used for, or derived thereof, have to be excluded from patentability under Article 53(b) of the European Patent Convention.

There are some specific legal questions that need to be resolved in this context: For example, 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."*

In the light of the patent applications presented in this research, the question arises of whether, for example, a company can claim biological material such as DNA sequences that occur in nature or stem from existing plant populations, or are derived at random. As is shown in the applications (such as WO2016011146), the companies not only try to claim the specific DNA sequences, but also all plants inheriting the relevant genetic information.

Thus, to make the provisions of Article 53(b) EPC effective, the interpretation of Article 3.2 of EU Directive 98/44 requires specific attention. In the light of the history of the patent directive, it has to be concluded that the wording "*produced by means of a technical process*" has to be understood as being relevant only for biological material (such as DNA sequences) being used in its isolated form, such as the insertion of DNA sequences into a genome by technical means.
Indeed, as the EU Commission in its Notice points out, Article 3.2 can not be understood to concern conventional plant breeding. Thus, plants and animals inheriting the relevant DNA cannot be

[6]reference
[7]http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN

claimed if they are derived from essentially biological processes. This interpretation now should be fixed in the Implementing Regulations of the EPC.

5. Demands

In conclusion, to make the prohibitions of Article 53(b) effective, the governments have to insist on the following rules for interpretation being integrated into the Implementing Regulations of the EPC:

- All methods used in conventional plant breeding, such as selecting processes and use of random mutations and genetic variations, have to be excluded.
- All plants and animals as well as breeding material and genetic elements used in, or derived from, conventional breeding have to be excluded.
- The scope of patents granted on methods of genetic engineering has to be restricted in a way any overlap with the prohibitions of Article 53(b) can be avoided.

No Patents on Seeds! has drawn up a draft text that can be used as a guidance on how effective rules for interpretation can be integrated into the Implementing Regulations of the EPC.