



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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Summary

In essence, the basis for European patent law, the so-called European Patent Convention (EPC), excludes plants and animals from patentability. As Article 53(b) of the EPC reads, no patents on plant or animal varieties may 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, the European Patent Office (EPO) has very often disregarded and undermined prohibitions in the EPC, granting thousands of patents on plants and animals in recent years.

Increasing number of patents

At present, in Europe, an increasing number of patent applications are being filed on plants and animals. More than 3000 patents on plants have already been granted – most of them covering genetic engineering. In the last 10 to 15 years, there has also been a steady increase in the number of patent applications being filed on plants derived from conventional breeding, i.e. not genetically engineered. More than 1500 such applications have been filed and more than 200 patents have been granted to date.

Patents on conventional breeding have nothing to do with the traditional understanding of patent law, or with giving fair rewards and incentives for innovation and inventions. Very often, based largely on trivial technical features, such patents actually abuse patent law, using it as a tool to misappropriate of biological resources needed for our daily food production.

It should be noted that the patents in this area are not limited to plants and seeds, but are also granted on the harvest, such as kernels, fruits and vegetables, and food production. For example, in 2016 patents were granted to the international companies Carlsberg and Heineken covering conventionally bred barley as well as the beer produced with it.

Growing market concentration

This development must be seen in the context of growing concentration in seed markets, food production and agriculture, globally and in Europe. In the very near future, Bayer (together with Monsanto) and DowDuPont are expected to control more than half of the global seed markets. Together with the third largest seed company, the Swiss-based Syngenta, around 60 percent of the international trade in seeds will be controlled by just three companies.

Patents are one of the most crucial legal and political mechanisms that benefit large-scale, industrial agriculture at the expense of small-scale, regional plant breeders and farmers. Put bluntly, patents put at risk the sustainability of our agriculture and our food security.

Far-reaching impact

Patents on conventional breeding will dramatically change the situation for farmers, growers and breeders. In future, farmers, growers or breeders who do not sign contracts with the patent holder will have no access to the patented seeds – neither for growing, for propagation nor further breeding.

The rise in the patenting of plants is of serious concern to many stakeholders, including traditional breeders, farmers who save, multiply or even breed their own seeds or animals. In addition, developing countries might be forced to allow patents on seeds through free trade agreements. Vegetable growers

and farmers will become dependent on just a very few companies. Consumers, food producers and retailers will find themselves in a situation where prices and choice in food products are decided by companies such as Monsanto.

As a consequence, agro-biodiversity will also decline if only a few companies are able to determine which patented “super seeds” will be grown in the fields. Agro-biodiversity is one of the most important pre-conditions for the future of breeding, environmentally-friendly agriculture and the adaptability of our food production to changing conditions, such as climate change. Seen from this angle, it is a development that is problematic not only for specific sectors or regions, but one that can threaten agro-biodiversity, ecosystems and the adaptability of our food production systems to meet challenges such as climate change. This makes it a huge risk for global food security and regional food sovereignty.

European Patent Office is serving the interests of industry only

In 2017, after protests from the public and criticism from EU institutions, the European Patent Office (EPO) adopted new rules for the interpretation of the European Patent Convention. For the first time, the EPO acknowledged that both the processes for breeding and the resulting plants and animals are excluded from patentability if the processes are considered to be “essentially biological”.

However, what is defined by the EPO as “essentially biological” is not in line with what is commonly considered to be “conventional breeding” (as the opposite of genetic engineering). According to the new rules, all plants and animals will still be patentable if they are identified as inheriting genetic variations or random mutations that are relevant for breeding.

Furthermore, there are still no provisions in place to limit the scope of patents. Under current practice, if plants or animals with specific breeding characteristics are patented, then all plants or animals with such traits will be covered by the patent, regardless of whether they are derived from methods of genetic engineering, from conventional breeding, or whether they naturally show those traits. This is an absurd situation that allows companies to monopolise a specific characteristic that could even occur in nature.

The recent patents on barley and beer granted to Carlsberg and Heineken are examples of patents which, according to the new interpretation of the patent law, will also be granted in future. The companies were granted patents on barley plants that produce kernels with random mutations. The patent covers the barley, the brewing process and the beer brewed with the barley. After many civil society organisations filed oppositions against these patents in 2017, the EPO confirmed that, based on the new rules, it was unlikely that such patents, based on random mutations, would be revoked.

Our analysis of recent patent data shows that the EPO and firms are exploiting this significant loophole to continue the patenting of plant and animal characteristics – in clear opposition to the public interest and the spirit of EU law. In 2017, the EPO repeatedly demonstrated an unwillingness to engage with civil society, allowing only representatives of industry and patent lawyers to attend its discussions and access information. It is clear that a fundamental reform of the EPO is required to ensure the EPO meets the usual standards of transparency and democratic accountability to be expected of a public body in the 21st century.

What needs to be changed

There are three crucial areas that need changing to make current prohibitions of patents on plant and animal varieties and essentially biological methods for breeding effective:

1. Definition of essentially biological processes

It has to be clarified that the term “essentially biological processes” covers all conventional breeding processes, including random mutagenesis, as well as all individual steps in the process, such as selection and / or propagation.

2. Definition of ‘products’ used or derived from breeding

It has to be clarified that all “products” used in or emanating from essentially biological processes are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information.

3. Limiting the scope of protection

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

1. A brief outline of the problem

The purpose of the patent system is to foster innovation by allowing inventors to recoup the cost of their research and development work through the application of intellectual property rights. Patents were originally developed for chemicals and mechanical products. Products or processes can be patentable if they fulfil criteria such as novelty, inventiveness and industrial applicability. If patents are granted, the patent holder can prevent others from the reproduction, use, sale and distribution of the invention for 20 years.

In recent decades, the patent system has been expanded from chemicals and mechanical products to human, animal and plant life. Since that, patents on plants and animals are at the centre of a broad public debate and legal controversy. The concept of treating plants and animals as inventions of industry goes against the ethical principles and fundamental values of European societies.

European patent law actually explicitly prohibits patents on plant and animal varieties. Nevertheless, the European Patent Office (EPO) continues to grant thousands of patents in this area.

The work of the coalition *No Patents on Seeds!* focusses specifically on putting an end to the patenting of conventionally bred plants.

1.1 Plants and animals are becoming “inventions”

At present, in Europe, an increasing number of patent applications are being filed on plants and animals. Around 3000 patents on plants have already been granted – most of them covering genetic engineering. In the last 10 to 15 years, there has been a steady increase in the number of patent applications being filed for plants derived from conventional breeding i.e. not genetically engineered. Around 1500 such applications have been filed and around 200 patents have been granted.

There is growing discontent over the role and practices of the EPO, which regards the granting of patents as a business and a service for industry, but which disregards wider public interests. In parallel, there are increasing concerns about market concentration in the field of plant and animal breeding. Companies such as Monsanto, DowDuPont, Syngenta and Bayer are the ‘seed giants’ that are increasingly attempting to monopolise seed, harvest and food production, in particular, through the abuse of patent law.

In the following chapters we have compiled an overview of recent developments and open questions. We also set out some demands and recommendations.

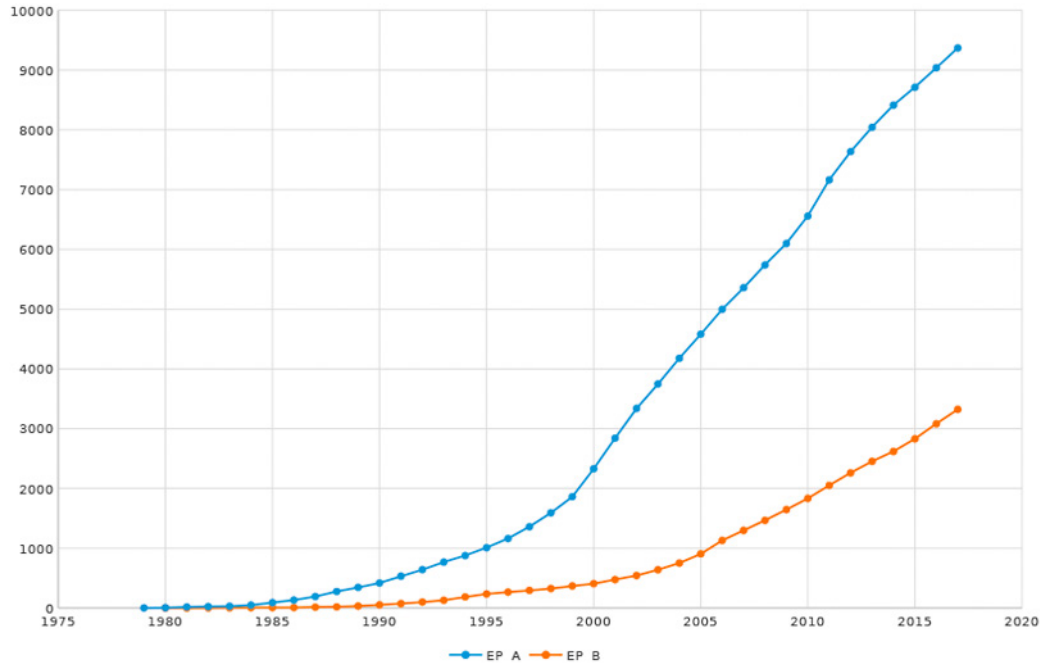


Figure 1: Number of patent applications and patents granted on plants at the European Patent Office in Munich (accumulated) Research according to official classifications (IPC = A01H or C12N001582).

1.2 Soaring concerns about the seed markets, agriculture and food production

Concerns about the patenting of plants and animals must be seen in the context of the growing concentration in food production and agriculture, globally and in Europe. Patents add to a picture of decreasing competition that benefits large companies, but is detrimental to small-scale, regional plant breeders and farmers - and ultimately to our food security. Furthermore, these patents are not restricted to seed production, they are also being granted on the harvest e.g. on kernels, fruit, vegetables and food production. For example, in 2016, patents were granted that cover conventionally bred barley, the process of brewing and the resulting beer.

In 2018, Monsanto is expected to merge with the German company, Bayer, which is also active in seed production. As a result, Bayer (Monsanto) would control around 30 percent of the international seed markets. The second largest seed giant, the US-based company DuPont, recently completed a merger with the US company, Dow AgroSciences to become DowDuPont, and now has a market share of around 20 percent. This means that just two companies, Bayer (Monsanto) and DowDuPont, will control more than half of the global seed markets. The third largest company in this sector is the Swiss company Syngenta, which was bought up by ChemChina, and controls a further approximately 10 percent of the trade in seeds.

Consequently, a very small number of large companies is becoming extremely powerful in regard to our daily food supply; with ever growing power to determine which plants will be bred, grown and harvested in future, and how much seed and food production will cost.

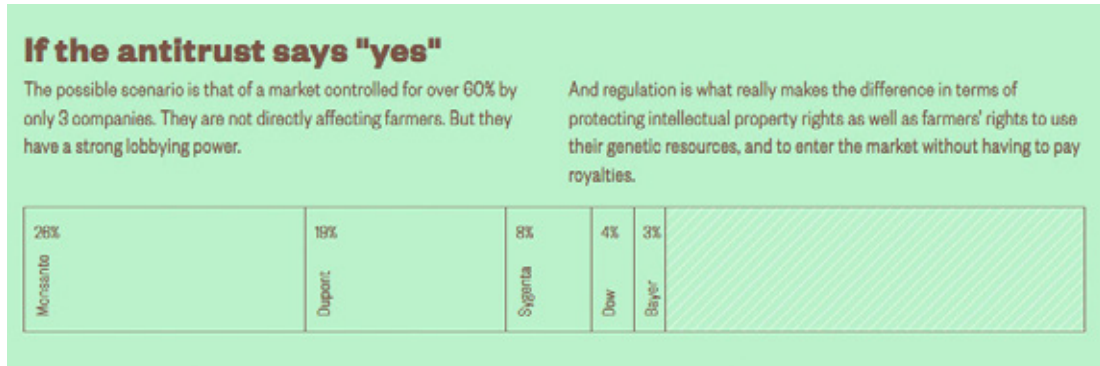


Figure 2: If the takeovers are not stopped, around 60 percent of the international seed markets will be controlled by just three companies. Source: <http://seedcontrol.eu/en/market.php>

The power of the seed giants will increase even more in the near future if they continue to be permitted to receive patents on conventional seeds. As patent holders gain an exclusive right to a specific plant or animal trait, patents on plants and animals can substantially restrict or hamper access to the genetic resources needed in plant breeding, thereby hindering the process of innovation in breeding. They do this both directly, by effectively privatising a specific plant trait that others may often no longer use in their own breeding programmes (or only after payment of a licence fee to the patent holder), and indirectly, by creating significant legal uncertainty for plant breeders about what plant material they may and may not use in their own work because the scope of patents is very often not clearly defined. This legal uncertainty affects smaller plant breeders most, and they are the ones who will also have to bear substantial costs for examining the scope and impact of patents that have been granted.

Such patents have nothing to do with the traditional understanding of patent law, or with giving fair rewards and incentives for innovation and inventions. Very often, based largely on trivial technical features, such patents actually abuse patent law, using it as a tool for the misappropriation of biological resources needed for our daily food production.

This development has raised many concerns amongst stakeholders, such as traditional breeders and farmers who save, multiply or even breed their own seeds or animals. There are further wider concerns that developing countries might be forced to allow patents on seeds via free trade agreements. Vegetable growers and farmers will become dependent on just a very few companies. Consumers, food producers and retailers will find themselves in a situation where prices and choice in food products is decided by companies such as Monsanto. Already in 2009, a research report from the University of Wageningen stated:¹

“For most crops only a few companies are controlling a large part of the world market. This makes a growing part of the global food supply dependent on a few companies. (...) Farmers and growers fear that their freedom of choice is threatened and that no varieties will be developed for certain crops that specifically meet their requirements (...).”

1 Louwaars N., Dons H., Overwalle G., Raven H., Arundel A., Eaton D., Nelis, A., 2009, Breeding Business, the future of plant breeding in the light of developments in patent rights and plant breeder's rights, University of Wageningen, CGN Report 2009-14 (EN) CGN Rap, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1720088



Figure 3: Patented food products are already on the market. For example, in 2011, patented broccoli was introduced in the UK by Monsanto under the brand of “Beneforte”.

These developments also affect areas which have not been previously considered in this context. For example, the big breweries Carlsberg and Heineken were granted several patents on barley used in the production of beer and other beverages. The patents cover barley derived from conventional breeding and cover the plants, the harvest, the process for brewing, malt and wort and all drinks produced with the patented barley.



Figure 4: Patents on beer were granted to Carlsberg and Heineken in 2016 and opposed by *No Patents on Seeds!* in 2017

If the current trend is not halted, big companies such as Bayer (Monsanto), DowDuPont, Syngenta and others will be increasingly in a position to decide what is grown and harvested and served as food in Europe and other regions.

The consequences of only a few companies being able to determine which patented ‘super seeds’ are grown in the fields will lead to a decline in agro-biodiversity. Agro-biodiversity is one of the most important preconditions for the future of breeding, environmental-friendly agriculture and the adaptability of our food production to changing conditions, such as climate change. Seen from this angle, it is a development that is problematic not only for specific sectors or regions, but one that can threaten agro-biodiversity, ecosystems and the adaptability of our food production systems to meet challenges such as climate change. This makes it a huge risk for global food security and regional food sovereignty.

2. Patents on seeds and plants granted in Europe

More than 3000 patents on plants and 1600 patents on animals have been granted in Europe since the 1980s. Nearly 10.000 patent applications on plants and more than 5000 patents on animals have been filed, many of them are still pending.

The process of patenting plants and animals started with the introduction of genetic engineering in plant production, but has meanwhile extended to conventional breeding: The EPO has already granted more than 200 patents on conventional breeding and more than 1500 patent applications have been filed, with roughly half of them still pending.

The number of patent applications in the conventional plant breeding sector has strongly increased within recent years. In the meantime, more than 30 percent of the total number of patent applications on plants are concerning conventional breeding.

The scope of many of the patents granted by the EPO is extremely broad and often covers the whole food chain, from the seeds to the production process and the end product for consumption. For example, in 2016, patents were granted that cover conventionally bred barley, the process of brewing and the resulting beer. These patents on plants and animals are an abuse of European patent law, designed to take control of the resources needed for our daily lives.

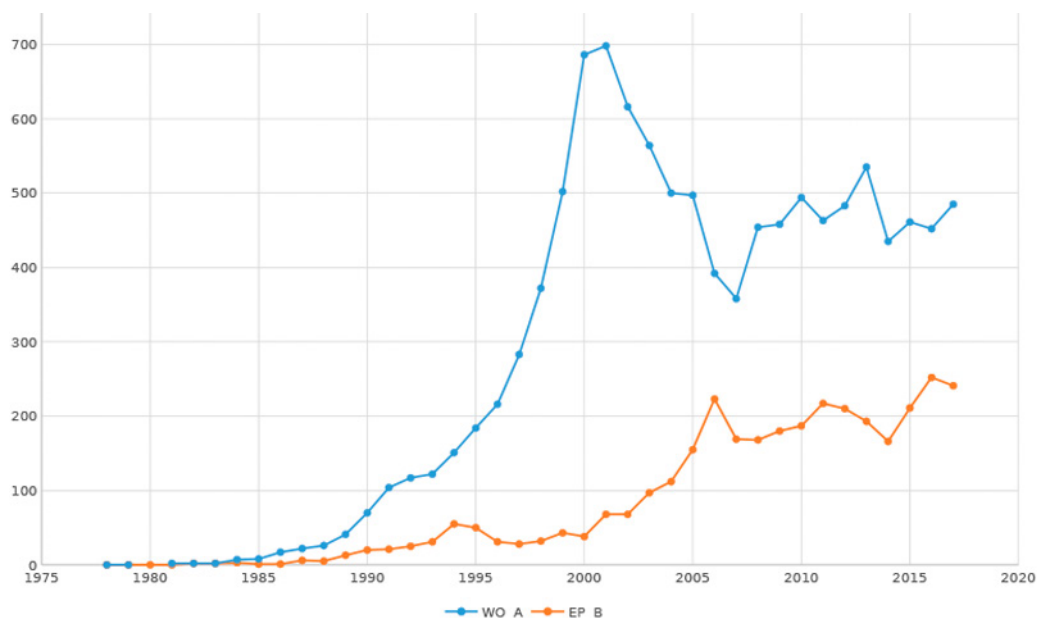


Figure 5: Patents on plants - number of patent applications on all plants under PCT/WIPO (WO A) as well as of patents on plants granted by the EPO (EP B) per year. Research according to official classifications (IPC A01H or C12N001582).

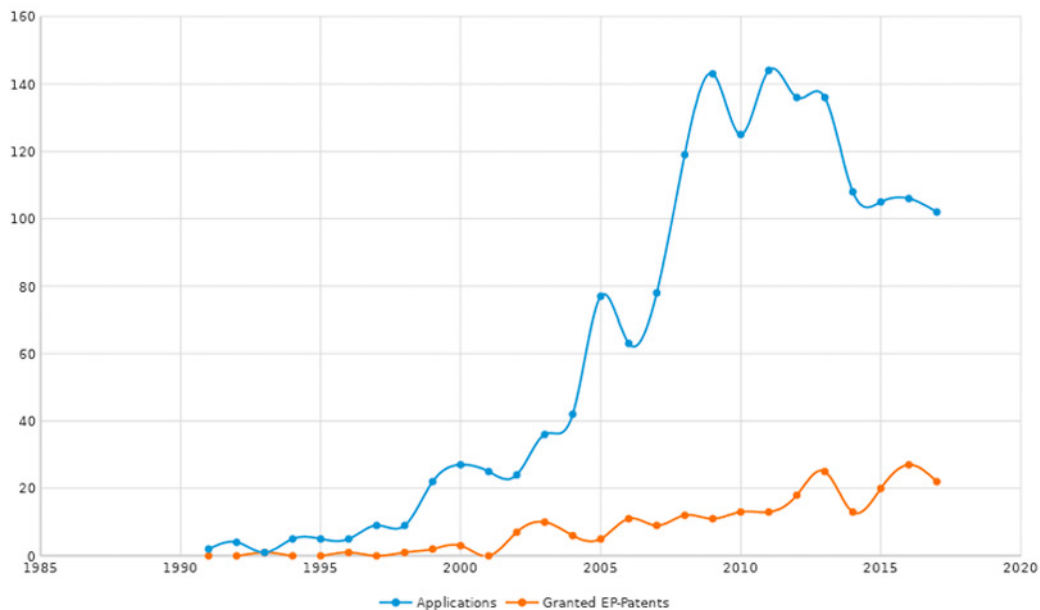


Figure 6: Number of patent applications (Applications) and patents granted on conventional plant breeding (Granted EP-Patents) by the EPO per year (own research).

In Europe, patents on conventional breeding are of much greater interest to big companies than those on genetically engineered plants. Such patents have much larger impact on breeders in Europe because genetically engineered plants are hardly grown in Europe at all. And also beyond Europe, if these patents are established and become part of free trade agreements they can affect breeders and farmers all over the world, including those who want to avoid genetically engineered plants and use seeds derived from traditional breeding and seed exchange.

2.1 New patent strategies

The EPO is granting an increasing number of patents on plants that are based on the usage of biodiversity, such as the identification of genetic variations detected in native traits, in commercial varieties or derived from random mutations.

According to our research, patents on genetic variations and mutations accounted for 65% of all patents granted on conventionally bred plants and animals in 2016.² In 2016, three of these patents were granted to the big breweries Carlsberg and Heineken. The patents cover barley plants derived from conventional breeding, their usage in brewing as well as the beer brewed thereof. The patents in question are based on random mutations in the genome of the barley. Specific mutations, which were already known to be useful, were selected by standard procedures.

In 2017, around 25 patents were granted on conventional breeding of plants, nearly all of them are based on methods similar to those in the beer patents: Patenting of genetic variations and their usage for breeding became the number one strategy in patenting conventional breeding. An overview is given in Table 1.

In many cases, the wording in the patent description and the patent claims is very vague. Frequently, no distinction is made between genetic engineering and non-inventive processes that have been used in conventional breeding for decades. The mixing of non-technical (non-patentable) methods for breeding with those of genetic engineering has huge implications. These patents cover all plants with the described characteristics, independently of the method that was actually used.

Even if the plant characteristics described in the patent are definitely derived from conventional breeding, the wording chosen in the patents often implies that the same result could also be achieved by technical intervention using methods of genetic engineering. This is the case with the beer patents granted to Carlsberg and Heineken in 2016: In the patents, techniques such as gene editing are mentioned, although they were not applied.

There is a specific ambiguity in the word “mutation” as used in these patents: It is used to describe a genetic variation that exists in a native trait, occurs spontaneously or is triggered by random mutagenesis. All of these methods are used in conventional breeding and are of non-technical and/ or non-inventive character. But the word “mutation” is also used to describe the result of old (transgenesis) or new (gene editing) methods of genetic engineering which are based on technical intervention.

What we see in these patents is the clever wording of patent attorneys using loopholes created by the EPO (see below). With these intended ambiguities, the patent holder wants to make sure that their patent is as broad as possible, and will not be rejected by the EPO for being non-technical.

² Then & Tippe (2017) Patent applications on plants derived from conventional breeding in 2016, http://no-patents-on-seeds.org/sites/default/files/news/report_patent_applications_on_plants_2016.pdf

Table 1: Patents on conventional breeding and underlying genetic variations granted by the EPO in 2017

EP Number	Patent-holder	Content	Ambiguities found in the patent
EP2635104	INRA	Stress-resistant plants	The stress resistance can be achieved by using native traits, random mutations or genetic engineering.
EP1551218	Dept. of Agriculture Australia	Plants with herbicide resistance	The resistance can be achieved with and without genetic engineering.
EP2087122	Biogemma	Method for producing maize with improved digestibility and reduced susceptibility to disease	The characteristics can be derived from random mutations or genetic engineering.
EP2400022	BASF	Sunflowers with herbicide resistance	The resistance can be achieved with and without genetic engineering.
EP2134159	BASF	Plants with herbicide resistance	The resistance can be achieved with and without genetic engineering.
EP1998607	Rijk Zwaan	Lettuce with resistance to Russet Spotting	The resistance was achieved by random mutations, but the patent covers all plants with the relevant characteristics.
EP2021477	INRA	Changed oil quality in brassica plants & related DNA sequences	The characteristics can be derived with and without genetic engineering.
EP2102349	Kansas University	Herbicide resistance in sorghum	The resistance can be achieved with and without genetic engineering.
EP1663466	Pioneer	Enhanced staygreen in plants	The characteristics can be derived with and without genetic engineering.
EP2455476	ENZA	Onion plants with enhanced resistance to diseases	The characteristics are derived from random mutations, but the patent covers all plants with the relevant characteristics.
EP2455479	ENZA	Tomato plants with enhanced resistance to diseases	See above
EP2455480	ENZA	Potato plants with enhanced resistance to diseases	See above
EP2455481	ENZA	Soybean plants with enhanced resistance to diseases	See above
EP2455474	ENZA	Cucumber plants with enhanced resistance to diseases	See above
EP2455478	ENZA	Grape plants with enhanced resistance to diseases	See above
EP1804571	Monsanto	Capsicum plants with enhanced resistance to diseases	Most relevant are crossing and selection by using DNA sequence information, but the patent covers all plants with the relevant characteristics.
EP2134839	BASF	Sunflowers with herbicide resistance	The resistance was achieved without genetic engineering, but the patent covers all plants with the relevant characteristics.

2.2 Impact on conventional breeding

Given that hardly any genetically engineered plants are grown in Europe, the around 2800 patents granted in this field have not had a significant impact. However, the approximately 200 patents recently granted on conventional breeding are already affecting plant breeding in many ways.

For example, in 2004, a patent was granted to Rijk Zwaan on lettuce derived from conventional breeding with resistance to aphids (EP 0921720). As this resistance is of interest to many breeders, five oppositions were filed by competing companies including Syngenta, Seminis (Monsanto) and Gautier, but the patent was upheld with some changes. As the PINTO database³ established by European Seed Association (ESA) shows, at the end of 2017, more than 300 varieties registered in Europe and developed by other breeders contained the licensed trait covered by this patent.

The example of Rijk Zwaan is just one of several showing how important patented native traits can become for a large number of plant breeders. The patented material might be licensed, or access might be blocked and just a single patent can have a wide impact – in a very similar way to patents on genetically engineered traits, which are one of the factors driving concentration in the US seed markets.

There are other examples in the PINTO database showing that single patents on conventionally derived traits can simultaneously impact the breeding of many varieties. By the end of 2017, there were only 55 patents listed in the database, but the number of varieties affected by these patents was around 880.

Patents on conventional breeding will dramatically change the situation for farmers, growers and breeders. In future, farmers, growers or breeders who do not sign contracts with the patent holder will have no access to the patented seeds – neither for growing, for propagation nor further breeding. This observation can already be made in countries like the US, where patents on seeds already play a much greater role than in Europe.

However, European plant breeders are also preparing to substantially restrict access and usage of their seeds. For example, in its terms and conditions for the sale of all its seeds, the Dutch seed company ENZA, which was granted several patents in 2017, restricts the usage of its seeds to only one period of cultivation. Any exchange, re-use, research and further breeding is completely prohibited. Those who acquire the products from ENZA have to sign up to these terms and conditions and automatically are caught in their patent trap.

This development is an extremely risky experiment, full of legal uncertainties for all European breeders. Looking to the high costs of patent litigation processes and the damaging penalties that can result, it has to be assumed that in the long run only the big companies will survive. In the end, the seed giants will be the ones to survive these ‘patent wars’ and also gain the most benefit.

³ <http://pinto.euroseeds.eu/>

Box: General terms and conditions of sale of Enza Zaden (2018)⁴

Article I – Definitions

5. Intellectual Property Rights shall mean all current and future intellectual property rights, including but not limited to plant breeder's rights, utility patent rights, patent rights (...).

Article II - Use (License) of the Products and Product Information

1. Enza Zaden grants the Buyer a non-exclusive, non-transferable and limited license for the duration of the Agreement to use the Products for the sole purpose of a single commercial production or cultivation and sale of Plant Material.

2. The Buyer must not use or cause or permit the use of the Products or Plant Material for any research, breeding, molecular or genetic analysis, crop, seed (re)production, propagation and/or multiplication or for any other purpose other than commercial production or cultivation of Plant Material in accordance with this Article.

2.3 The new rules at the EPO

Patents on plants and animals derived from conventional breeding led to protests by civil society organisations as well as strong criticism from EU institutions; this resulted in resolutions being passed by the EU Parliament, the EU Commission issuing statements and EU member states making decisions (see Annex). In essence, all these political activities aimed to exclude processes for conventional breeding as well as the respective plants and animals from patentability.

In response, in 2017, the EPO adopted new rules for interpretation of the European Patent Convention.⁵ The decision seems to have eased some of the concerns raised. For the first time, the EPO acknowledged that both the processes for breeding and the resulting plants and animals are excluded from patentability if the processes are considered to be “essentially biological”.

However, what is defined by the EPO as “essentially biological” is not in line with what is commonly considered to be “conventional breeding” (as the opposite of genetic engineering). According to the new rules, all plants and animals will still be patentable if they are identified as inheriting genetic variations or random mutations that are relevant for breeding.

Furthermore, there is no clear distinction between the non-patentable methods of breeding and genetic engineering. If plants or animals with specific breeding characteristics are patented, then all plants or animals with such traits will be covered by the patent, regardless of whether they are derived from methods of genetic engineering, from conventional breeding, or whether they naturally show those traits.

⁴ www.enzazaden.com/-/media/Files/enza-zaden/general/general-terms-and-conditions.ashx

⁵ www.epo.org/news-issues/news/2017/20170629.html

Patents on barley and beer granted to Carlsberg and Heineken are examples of patents which, according to the new interpretation of the patent law, will also be granted in future. The companies were granted patents on barley plants that produce kernels with random mutations. The patent covers the barley, the brewing process and the beer brewed with the barley. After many civil society organisations filed oppositions against these patents, the EPO confirmed that, based on the new rules, it was unlikely that such patents would be revoked.

This recent development again raised concerns and strong criticism. This was made clear in a letter dated December 2017, addressed to the EU Commission. The letter was jointly sent by *No Patents on Seeds!*, COPA/COGECA which is the biggest umbrella organisation of farmers in the EU, the organic sector in the EU represented by IFOAM and the European Consortium for Organic Plant Breeding (ECO-PB). These organisations jointly state:

“(...) it became clear that the EPO and groups of experts with close ties to this organisation are looking for ways to continue granting patents on plants and animals, including on native traits as well as mutations. This situation is unacceptable for farmers, breeders and consumers, as it restricts access to genetic material for further innovation and totally ignores the concerns of European citizens. The signatory organisations are opposed to any kind of patenting of plants, animals, genes and genetic traits that can be found in nature or obtained through mutagenesis. (...) Representing almost all seed users, the signatory organisations regret that the EPO, which is a powerful organisation, refuses to listen to our concerns.”⁶

2.4 What is an invention and what is just conventional breeding?

From the perspective of patent law, there is a key distinction to be made between real technical inventions and normal conventional breeding. In European patent law, there is a special category called “essentially biological processes” for the category of non-technical, non-inventive, traditional breeding, which is explicitly excluded from patentability. One reason for the exclusion under Article 53(b) is to provide plant breeders with freedom to operate (i.e. to access plant material for their own breeding programs) as also foreseen under the plant variety protection (PVP) system. But in fact, as shown above, patents as granted do not make a distinction between methods used in conventional plant breeding and genetic engineering techniques (see Table 1).

Currently, there is a great deal of confusion with respect to the definition of “essentially biological processes”. This confusion has been intentionally created by the EPO and some other powerful players with very particular interests. These stakeholders do not want European breeders to keep their freedom to operate – they want instead conventional plant breeding to become part of their system of dependencies based on monopoly patents. This system will not only hamper competition in plant breeding; it also aims to control large parts of agriculture and food production.

⁶ <http://www.copa-cogeca.be/Download.ashx?ID=1759616&fmt=pdf>

Different figures on patents being granted on conventional breeding

There is a huge discrepancy between what the EPO considers to be conventional breeding or “essentially biological” (and therefore non-patentable) and what is generally considered to be conventional breeding by the breeding sector, farmers and the wider public.

This discrepancy is also mirrored in the statistics on patents: While the *No Patents on Seeds!* figures cover all practices used in conventional breeding, the EPO presents much lower numbers. The reason: Without any justification in science or breeding practice, the EPO considers usage of random mutations, or even selection on its own without prior crossing, to be not “essentially biological”. As a result, the EPO only lists about 80 patents that were granted on the conventional breeding of plants, whereas *No Patents on Seeds!* is aware of more than 200 patents.

What is the concept of conventional breeding?

Conventional breeding is much more than a combination of crossing and selection. It always starts from a broad range of biodiversity using native traits and commercial varieties, mutations and genetic variations. In a first step, this richness of genetic variability is screened and selected according to suitable characteristics for the breeding project. After identifying the relevant genes or phenotypical conditions, crossings and further selections can take place. Unlike genetic engineering, the genetic variability used in conventional breeding emerges from mechanisms inside the cell, and is not inserted into the genome via technical interventions.

In this context, some conventional breeders also use a method called random mutagenesis. In this method, UV-light or chemical compounds are used to speed up the rate of mutations in the cells. As a result, the genetic variability within the genome will be augmented (given the range of different mutations that will occur) within a shorter period of time than could normally be expected. This higher variability is used as a starting point for selection, followed by crossings and further selections.

Usage of random mutations is non-inventive and non-technical in the sense of patent law and has been used for decades. This method is a tool within the concept of conventional breeding; it does not change the concept.

What are real technological inventions?

The technically mostly trivial processes of augmenting genetic variability at random in the process of conventional breeding must not be confused with genetic engineering. Techniques such as transgenesis or gene editing enable the direct technical intervention at the level of the genome. These tools are not used to establish a higher variability in the gene pool but to achieve very distinct changes in the genome.

The distinction between conventional breeding and technological methods for changing the genome can be made from both a historical and biological point of view. In any case, this distinction is decisive for the interpretation of what is meant by “essentially biological” in the sense of patent law to be non-technical and non-patentable. If this distinction is not clear, the legal provisions that prohibit patents on “essentially biological processes for the breeding of plants and animals” cannot be implemented.

Confusion – in the interests of patent holders, patent attorneys and the EPO

As shown above, the EPO currently only regards a combination of crossing and selection as non-patentable. The office still grants patents on genetic variability that is the basis for conventional breeding. As shown, crossing and subsequent selection are steps that usually occur at a later stage of the breeding process, after the prior steps of identifying mutations and other breeding characteristics. Under the current approach of the EPO, if patents have been granted on these first steps, all later steps in the breeding process may also be patented. The interest in “down-stream control” is evident in the Carlsberg and Heineken patents on barley: Two of the granted patents concern random mutation in barley, while a third patent (EP2575433) covers the combination of these two barley plants by further crossing.

The economic interests behind the patenting of genetic diversity used in conventional breeding are all too evident: Those who identify genetic variations and file patents on them can also control all subsequent steps in breeding processes, building on those variations and the usage of food plants containing those variations. This is in the interests of the seed giants as well as big food companies / breweries. The situation is also in the interests of the EPO, which looks upon the examination and granting of patents as a business. Finally, patent attorneys also benefit from this expansion of their business sector. However, this is not in the wider public interest.

3. Case studies: Granted patents on the conventional breeding of plants

The following overview presents some examples of patents that were granted by the EPO within the last few years. The patents are grouped in three categories according to the wording of their claims: (i) patents on a combination of crossing and selection, (ii) patents on the step of selection (without crossing); and (iii) patents on random mutations and genetic variations.

While, after heavy criticism and changes to its rules in June 2017, the EPO will in future no longer grant patents that are exclusively based on crossing and selection, it still regards patents on the step of selection (without crossing) and on random mutations and genetic variations as patentable (see Annex 1).

Several of the patents were opposed by civil society organisations cooperating with *No Patents on Seeds!* (see Table 2).

Table 2: Overview of legal cases brought by *No Patents on Seeds!* against patents on plants

Patent number	Company	Content	Current state of proceedings
EP 2373154	Carlsberg/Heineken	Barley & Beer	Opposition filed 2016
EP 2384110	Carlsberg/Heineken	Barley & Beer	Opposition filed 2016
EP 2575433	Carlsberg/Heineken	Barley & Beer	Opposition filed 2017
EP 2134870	Monsanto	Selection of soybeans	Opposition filed 2014 opposition rejected in 2017, appeal under preparation
EP 1515600	Syngenta	Tomato	Opposition filed 2016
EP 1962578	Monsanto	Melon	Opposition filed 2011 patents revoked in 2016 appeal pending
EP 1597965	Monsanto	Severed broccoli	Opposition filed 2013
EP 1812575	Monsanto	Tomato	Opposition filed 2014 Patent revoked 2014
EP 2140023	Syngenta	Pepper	Opposition filed 2014

Patents on crossing and selection

'Super broccoli'

In 2002, the EPO granted a patent on broccoli (EP 1069819) with a high content of glucosinolates which supposedly have health benefits. The plants stem from crossings of wild variants of broccoli (native traits) with commercial varieties. The patent covers the plants, the seeds and the harvested food. The patent claims read:

I. A method for the production of Brassica oleracea with elevated levels of (...) glucosinolates (...) which comprises:

- (a) crossing wild Brassica oleracea species with Brassica oleracea breeding lines; and,
- (b) selecting hybrids with levels of (...) glucosinolates (...), elevated above that initially found in Brassica oleracea breeding lines.

9. An edible Brassica plant produced (...)

10. An edible portion of a broccoli plant (...)

II. Seed of a broccoli plant (...)⁷

The patent is owned by Monsanto and the broccoli is marketed under the brand "Beneforte" as "super broccoli" in countries such as the US and UK. The patent, together with a patent on tomatoes with a reduced content of water (EP 1211926), became the precedent case at the EPO for patents on plants derived from conventional breeding. Following changes to the EPO rules in June 2017, such patents will no longer be granted in Europe as the plants are derived exclusively from crossing and selection.

Monsanto's Indian Melon

In May 2011, the US company Monsanto was granted a European patent on conventionally bred melons (EP 1 962 578). These melons which originally come from India, have a natural resistance to certain plant viruses. Using conventional breeding methods, this type of resistance was introduced to other melons and is now patented as a Monsanto "invention". The actual plant disease, cucurbit yellow stunting disorder virus (CYSDV), has been spreading through North America, Europe and North Africa for several years. The Indian melon, which confers resistance to this virus, is registered in international seed banks as PI 313970.

Monsanto can use this patent to block access to all breeding material inheriting the resistance derived from the Indian melon. The patent might discourage future breeding efforts and the development of new melon varieties. It is already known that further breeding will be necessary to produce melons that are actually protected against the plant virus. The patent was opposed by several organisations in 2012 with the support of *No Patents on Seeds!*. In the first instance, the patent was revoked by the EPO in 2016 due to technical reasons. Since then an appeal has been filed against the decision, but the final outcome of this case is still pending.

⁷ Patent (B2 publication) published on 18.01.2017

<https://data.epo.org/publication-server/pdf-document?pn=1069819&ki=B2&cc=EP>

Severed broccoli

In June 2013, Seminis, a company owned by Monsanto, was granted patent EP 1597965 on broccoli that was (conventionally) bred to have a certain shape to make mechanical harvesting easier. The patent covers the plants, the seeds and the “severed broccoli head” which is used for food. It additionally covers a “plurality of broccoli plants (...) grown in a field of broccoli.” The method used to produce these plants was purely crossing and selection. In May 2014, an opposition was filed with support of *No Patents on Seeds!*. The case is still pending in 2018.

Wild pepper

In May 2013, the EPO granted a patent to Syngenta claiming insect-resistant pepper and chilli plants derived from conventional breeding (EP2140023). The patent covers the plants, fruits and seeds and even claims the growing and harvesting of the plants as an invention. The pepper plants were produced by crossing a wild pepper plant (with the insect resistance) from Jamaica with commercially produced pepper plants. Marker genes that go along with the desired insect resistance were identified. Although this kind of insect resistance already existed in nature, Syngenta was nevertheless able to claim the insect-resistant pepper plants, their seeds, and their fruits as an invention. The patent covers all steps of breeding and use of the plants, including selection, growing of the plants and harvesting the seeds and all relevant plant varieties.

The patent granted to Syngenta was opposed with the help of *No Patent on Seeds!* in February 2014 by a coalition of 34 NGOs, including farmers’ organisations and breeders from 28 countries. In 2018, the decision about the patent is still pending.

Syngenta’s healthy tomatoes

A monopoly on specific tomatoes with a higher content of healthy compounds known as flavonols was granted by the EPO to the Swiss company Syngenta in August 2015. The patent covers the plants, the seeds and the fruits. Patent EP1515600 describes the crossing of wild tomatoes with domesticated varieties. The original tomatoes were collected in countries such as Peru. In 2016, the patent led to the filing of a record mass opposition by around 65,000 individuals, supported by *No Patents on Seeds!*. In 2018, the decision on the opposition is still pending.

Patents on the selection of plants

Discoloration of surface in lettuce

In March 2013, a patent was granted to Rijk Zwaan, a company based in the Netherlands. It covers lettuce which shows less discoloration of its surface after cutting and looks fresh for a longer period of time (EP1973396). In this case, a trivial method for selecting plants (cutting and then observing whether it starts to go brown) was claimed as an ‘invention’. It covers plants, progenies, parts of the plant, the seeds and the food. All relevant plant varieties are also within the scope of the patent. A similar patent was granted to the same company in 2013 covering many more plant species (EP1988764). The wording of the claims covers lettuce, endive, chicory, potato, sweet potato, celeriac, mushrooms, artichoke, eggplant, apples, bananas, avocado, peaches, pears, apricots, mangos and other plants.

Selection of soybeans

In February 2014, the European Patent Office (EPO) granted a patent to Monsanto on screening and selecting soybean plants adapted to certain climate zones (EP2134870). The plants supposedly have higher yields in different environmental conditions. The soybeans concerned are wild and cultivated species from Asia and Australia. According to the patent, more than 250 plants from “exotic” species were screened for variations in climate adaption potential and variations in the period of time needed for the beans to mature. Monsanto has thereby gained a monopoly on the future usage of hundreds of natural DNA sequence variations in the conventional breeding of soybeans. In 2017, oppositions filed with the support of *No Patents on Seeds!* were rejected. The final outcome of this case is still pending.

Patents on random mutations

The big breweries Carlsberg and Heineken jointly filed applications for patents on barley used for the production of beer and other beverages. The patents, EP2384110 and EP2373154, were granted by the European Patent Office (EPO) in 2016. They cover barley plants derived from conventional breeding, their usage in brewing as well as the beer brewed thereof.

The patents in question are based on random mutations in the genome of the barley. Kernels were brought into contact with chemicals and in reaction showed an increase in their genetic variability. Thereafter, specific mutations, already known to be useful, were selected by standard procedures. The kernels are supposedly more suitable for brewing beer that, it is hoped, will keep its fresh taste over longer period of time.

Furthermore, the EPO granted a third patent (EP2575433) that covers a combination of the characteristics of the barley plants achieved by further crossings. Each of the three patents covers the plants, the harvest, the process for brewing, malt and wort and all drinks produced by this method. *No Patents on Seeds!* and others filed an opposition against the patents in 2017.

There are several other examples of such patents being granted that are documented in research carried out by *No Patents on Seeds!*. Table 3 gives an overview of examples from 2013.

Table 3: Overview of some patents granted by the EPO on conventional breeding, examples from 2013

EP number	Company	Species	Breeding method	Claims
EP 1786901	Dow AgroSciences	cereal plants	mutagenesis or genetic engineering	seed, feed, plant
EP 1708559	Arcadia	wheat	mutagenesis	DNA, selection
EP 1931193	Enza Zaden	cucumber	marker selection	plant, seed, fruits, marker
EP 2142653	Monsanto	cotton	exposure to external factors	methods
EP 2240598	Enza Zaden	cucumber	marker selection	selection
EP 1973396	Rijk Zwaan	lettuce	screening discoloration	plant, seed, products
EP 1420629	Northwest Plant Breeding	wheat	mutagenesis and genetic engineering	plant, parts, DNA
EP 0965631	Consejo Superior	sunflower	mutagenesis	oil, plants, progeny
EP 2115147	Enza Zaden	lettuce	mutagenesis	plants, methods
EP 1261252	DuPont	sunflower	mutagenesis	plant, methods, seed, pollen
EP 1804571	De Ruiters Seeds / Monsanto	pepper	marker selection	plant, screening, method of introducing genes
EP 2140023	Syngenta	pepper	marker selection	plant, seed, fruit
EP 1853710	Rijk Zwaan	all species	homozygous plant	stop of meiosis (also genetic engineering), methods
EP 1597965	Seminis/ Monsanto	broccoli	crossing and selection	plants, seeds, harvest
EP 2244554	Nunhems BV	onions	selecting for plant components	plants, seeds, harvest
EP 1263961	Limagrain	wheat	marker selection	plant, grain, flour
EP 1874935	DuPont	maize	DNA, marker selection, crossing and selection, genetic engineering	plants, seed, progeny, selection, crossing and selection, crossing (“introgressing”)
EP 1947925	Syngenta a.o.	wheat	marker selection, mutagenesis, genetic engineering	plants, seeds, method producing food
EP 1503621	Syngenta	watermelon	treepleid breeding	watermelon
EP 2114125	University of Kansas	sorghum	marker selection, genetic engineering	plants, seeds, DNA
EP 2255006	Semillas Fito	tomato	marker selection	selection
EP 1988764	Rijk Zwaan	many species	screening for discoloration, mutagenesis	screening
EP2158320	Bayer	maize	Selecting content of amylose, any method	flour and food which contains the starch
EP2173887	Biogemma	maize	marker selection	grain, usage in feed
EP 1812575	De Ruiters Seeds / Monsanto	tomato	marker selection, crossing, introgression	plants, seeds, fruits, crossing (“transfer of nucleic acid”)

4. Patents on farm animals

The European Patent Office has already granted several patents on the conventional breeding of animals. In particular, in 2007/2008 several patents were granted on the breeding of pigs and cattle. Patents on animals can have a huge impact on agriculture: For example, if patents on cattle are granted, the farmers can still sell the milk and meat but cannot use the animals for further breeding without the consent of the patent holder.

The following overview shows some of the patents on animal breeding that were granted by the EPO in the last few years. Most of the patents were revoked after opposition by civil society organisations. However, if the patenting of conventional plant breeding is not stopped, the EPO will also continue to grant patents on conventionally bred animals. From a legal point of view, there is no difference between plants and animals in patent law.

Patent EP1257168 was granted in 2005. It claimed sperm cells frequently used for the artificial insemination for cattle and pigs. The “invention” was to sort the sperm cells according to whether they would produce male or female offspring. By filing such patents, large parts of the breeding process can be controlled. The patent was revoked after opposition by Greenpeace and members of the Green Group in the European Parliament. But there are other patents in this area that are still valid.

In 2008, the EPO granted a patent on the breeding of pigs (EP 1651777). The patent was based on the usage of genetic conditions that are inherited as native traits in all European pig races. Originally, the patent was filed by the US-based company Monsanto. The patent, for example, described the screening of pigs to identify animals which had lean meat. Pigs derived from the process and their offspring were also within the scope of the patent. A broad coalition of farmers, environmental organisations and individuals filed an opposition against the patent and it was revoked in 2010.

Patent EP 1330552, granted in 2007, was the first European patent on dairy cows. The patent described a genetic condition influencing milk quality. The patent claimed this genetic condition and the process for selecting the cows inheriting it naturally. Further, the patent claimed genetically engineered cows. Oppositions were filed by German dairy farmer organisations together with development organisations and others. The patent was revoked in 2015.

Patent EP1141418 was granted in 2007 and concerned mechanisms of inheritance described as quantitative trait locus (QTL), which refers to animal characteristics that very often are based on the interaction of several DNA sequences. The patent was based on an effect generally known as imprinting: In QTLs some characteristics are expressed in different ways depending on whether the genetic conditions stem from the female or the male parent. The patent was revoked in 2010 after oppositions from civil society groups.

Patent EP 1506316 was granted in 2008. The patent described how to cross livestock to produce offspring of economic interest. The selection of the animals was based on genetic conditions that were already known. The patent was a business idea rather than an invention. The patent was revoked in 2012 after oppositions from civil society groups.

In 2015, a patent was granted on oysters (EP2184975). According to the patent, oysters from the Atlantic, the Pacific or the Indian Ocean were to be crossed with oysters from the Mediterranean Sea to make them resistant to pest infections. The actual process used here is to jointly place the oysters in a “tank containing water”. The claims cover the hatchery and the oysters.

In 2016, it was made public that the EPO wanted to grant a patent on salmon fed with specific plants (EP1965658). The EPO informed the Australian applicant that the patent was ready to be granted within the next few months. The patent claims the salmon and the fish oil. Food derived from these salmon is supposed to have a higher content of Omega 3 fatty acids, which are often described as having health benefits. The granting of the patent was stayed only after public protests.

5. What needs to be changed

The basis for European patent law, the so-called European Patent Convention (EPC), in essence excludes plants and animals from patentability. As Article 53(b) reads, no patents on plant or animal varieties may 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, in recent years the EPO has granted thousands of patents on plants and animals, mostly eroding these prohibitions in the EPC.

There are three crucial areas that need changes to make current prohibitions of patents on plants and animal varieties and essentially biological methods for breeding effective:

1. Definition of “essentially biological processes”

It has to be made clear that the term “essentially biological processes” covers all conventional breeding processes, including random mutagenesis, as well as all individual steps in the process, such as selection and / or propagation.

2. Definition of ‘products’ used or derived from breeding

It has to be made clear that all “products” used in or emanating from “essentially biological processes” are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information.

3. Limiting the scope of protection

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

The necessary changes can be brought about by clarifications in the EU patent directive 98/44/EC, the Implementing Regulations of the EPC, changes to the EPC, or as a first step, in national legislation (for more details see Annex 1).

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 frame work 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.

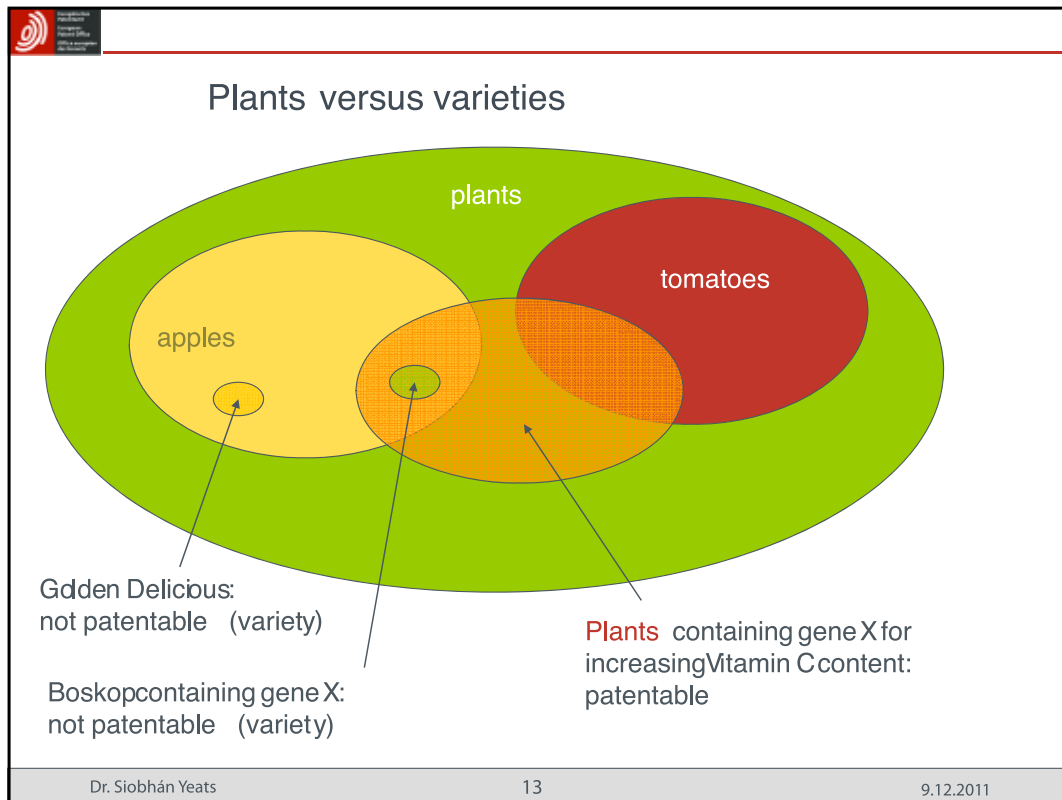


Figure 7: This slide shows how the European Patent Office currently interprets the prohibition of patents on plant varieties. While it is not possible to patent a defined variety of apple with a higher content of vitamin C, it is possible to grant a general claim on plants with an elevated content of 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>

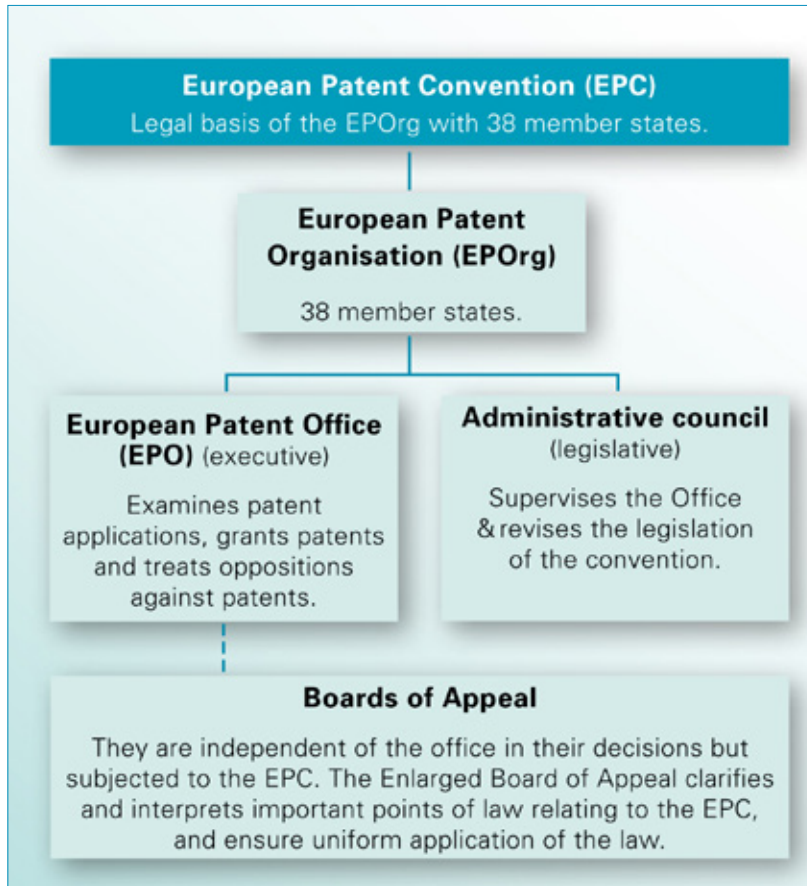


Figure 8: Structure of European Patent Organisation, EPOrg (source: Lebrecht & Meienberg, 2014)

The two Boards of Appeal are supposedly, at least partially, independent of the EPO in their decisions. However, all members of the boards and divisions are employed or appointed by the European Patent Organisation, including some external members who are part of the Enlarged Board of Appeal. The Enlarged Board of Appeal cannot be addressed directly either as an opponent or appellant. The decision on whether a case can be referred and which questions should be forwarded to the Enlarged Board of Appeal is taken by EPO institutions such as the Technical Board of Appeal and the President.

The structure of the EPOorg is not designed to foresee real independent legal supervision and is not controlled by international courts. This is a highly problematic situation for the overall functioning of the patent office. The EPO derives its budget from granting and examining patents. Its budget is mostly based on fees from patent holders (revenue from patent and procedural fees in 2016: 1.813 million € with steady increase over last years). Consequently, the patent office has its own vested interest in receiving applications and granting patents.¹⁵ Patent applicants - not society in general - are the real clients of the EPO. Industry and the EPO are both on the same side of the coin, with no independent judicial control.

¹⁵ Financial Statements Accounting Period 2016 [http://documents.epo.org/projects/babylon/eponet.nsf/0/01A11C90581E4824C12581590052FFCo/\\$File/epo_financial_statements_2016_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/01A11C90581E4824C12581590052FFCo/$File/epo_financial_statements_2016_en.pdf)

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 takes 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 BUSINESS-EUROPE 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.¹⁶

The Institute of Professional Representatives at the European Patent Office (epi) represents the European patent attorneys¹⁷. There are thousands of registered European Patent Attorneys in Germany as well as in the UK¹⁸. Patent attorneys, law companies, legal experts and consultants are all earning 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’ of its own.

While the stakeholders participating at the Administrative Council meetings such as BUSINESS-EUROPE or epi are heavily weighted in favour of vested interests in obtaining patents, other civil society organisations are not represented at all. At the same time, delegates from contracting states are mostly part of the ‘patent system’, so that effective political control and representation of the interests of the general public can hardly be expected.

As a consequence, the European Patent Organisation has to be seen as a mechanism designed to push through patents to satisfy vested economic interests; there are no independent controls in place, nor any participation from broader public. Consequently, the EPO is driven largely by its own economic interests and its affiliated patent industry.

¹⁶ <https://www.businesseurope.eu/>

¹⁷ <http://www.patentepi.com/en/the-institute/list-of-professional-representatives/>

¹⁸ <http://www.epo.org/applying/online-services/representatives.html>

Previous research in 2014 shows around 4000 patent attorneys in Germany and 2000 in UK.

The European Union, WIPO, TRIPS and TTIP

There are some other regulations relevant to European patent law.

1. The EU Patent Directive 98/44/EC

The most significant of these is an EU Directive (Legal Protection of Biotechnological Inventions 98/44/EC)¹⁹ that was adopted by the EU Parliament and EU member states in 1998. The EU Directive 98/44/EC was adopted in the historical context of the introduction of methods for genetic engineering. In Article 4, the Directive requests patents are granted on “inventions which concern plants or animals”, but does not allow patents on plants and animals as such.

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.”

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. Most relevant in this context are:

- Article 4, 2 of the Directive which became Rule 27 (b) of the EPC. It deals with patents on inventions concerning plants and animals that are not confined to a particular plant or animal variety.
- Article 2, 2 of the Directive which became Rule 26 (5) of the EPC. It deals with the definition of essentially biological breeding methods.

There are substantial reasons to assume that the legislator, when adopting the Directive 98/44/EC, 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 engineering, but not on methods applied in ‘conventional’ breeding.

2. The Unitary Patent of the EU

In future the EPO will be granting patents with a “unitary effect” under the so-called new “Unitary Patent” system²⁰ that is meant to ensure supranational protection in the Member States of the EU. For the first time there will be a European patent court, the so-called “Unified Patent Court”²¹.

However, this patent court is unlikely to solve current difficulties. For many years there was an expectation that the European Union would draw up an EU patent system that would enable independent legal control of European patents through the European Court of Justice (Court of Justice of the European Union). It appears though that the new Unified Patent Court will not be placed under the jurisdiction

19 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044>

20 <http://www.epo.org/news-issues/issues/unitary-patent.html>

21 <http://www.unified-patent-court.org/>

of the European Court of Justice as was originally planned. According to internal meeting protocols, it was the UK government together with BUSINESSEUROPE who prevented the European Court of Justice from becoming the highest legal instance at a last minute meeting in October 2012, just before the decisive vote. As a result, the influence of the ‘patent industry’ on the jurisdiction of the new court is likely to become very similar to the influence it has on the EPO institutions.

A further problem is that no specific regulations are foreseen at the Unified Patent Court that would allow non-profit organisations to bring cases at a reduced cost. Thus, the potentially extortionate costs of bringing a case to the patent court will make it highly unlikely that non-commercial interests will play a major role.

The unitary patent system will also raise problems for several member states: For example, in regard to patents on seeds, in many countries, such as Austria, patents granted by the EPO were not validated. Consequently, the patents did not have any effect on breeders active in these countries. But under the unitary patent system, all patents granted by the EPO will be automatically validated on the national level. In parallel, the costs to invalidate these patents at the Unitary Patent Court are very high.

As a result, the Unitary Patent System will become a huge business for patent lawyers and some companies, but might be detrimental to the innovation and future development of many technical sectors in many member states. The risk of over-patenting and of so-called patent trolls becoming active will substantially increase and thereby hamper competition, innovation and technological development. This problem will concern not only, but also, the breeding sector.

Finally, the new unitary patent system will introduce a ‘limited breeders’ exemption’. Such a legal provision is already foreseen in some national patent legislations, such as Germany. This provision might be seen as progress, however, it suffers from severe limitations since the breeders are only allowed to use patented material for further breeding. But the exemption does not allow the marketing of the new varieties derived from breeding with patented material. Consequently, many legal uncertainties remain as an obstacle in plant breeding and innovation.

3. Other international regulations: WIPO, TRIPS and TTIP

In general, most patents in Europe are applied for and granted through the EPO – national patent offices of the EU Member States only play a minor role in examining and granting patents. It is, however, possible to file patent applications at the WIPO (World Intellectual Property Organisation)²² under the International Patent System (PCT). WIPO does not grant any patents but forwards European patent applications to the EPO for examination.

Another relevant international treaty is the TRIPS agreement (trade-related aspects of intellectual property rights)²³ which is governed by the World Trade Organisation WTO. In this context, it is worth noting that according to TRIPS it is not necessary to issue patents on plants and animals (Art 27, 3)²⁴.

22 <http://www.wipo.int/portal/en/index.html>

23 http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

24 http://www.wto.org/english/docs_e/legal_e/27-trips.pdf