



European patents on plants and animals – is the patent industry taking control of our food?

Report published by "No Patents on Seeds!", 2014
Christoph Then & Ruth Tippe

www.no-patents-on-seeds.org

no patents on seeds

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Summary

This report illustrates how patents are on the verge of breaking through acceptable boundaries and putting our genetic resources at risk. Will our daily food soon be controlled by big corporations and the patent industry, or will our politicians make decisions to ensure that patents on plants and animals are prohibited?

We are at a critical stage: The seeds market is already highly concentrated in several sectors, including seeds for vegetables, maize and soybeans. According to recent reports, only five companies control 75 percent of the EU maize market, and same number of companies control 95 percent of the EU vegetable seeds market.

The European Patent Office (EPO) has already granted several thousand patents on plants and seeds, with a steadily increasing number of patents on plants and seeds derived from conventional breeding. Around 2400 patents on plants and 1400 patents on animals have been granted in Europe since the 1980s. More than 7500 patent applications for plants and around 5000 patents for animals are pending. The EPO has already granted more than 120 patents on conventional breeding and about 1000 such patent applications are pending. The scope of many of the patents that have been granted is extremely broad and very often covers the whole food chain from production to consumption. These patents are an abuse of patent law, designed to take control of the resources needed for our daily living.

In 2013, the EPO granted several patents on plants. These included patents on peppers bred from wild varieties originating from Jamaica, tomatoes that were developed using the international gene bank in Germany, sunflowers from random mutagenesis and a selection of wild relatives of soybeans found in Asia and Australia.

Analyses of EPO decision-making in recent years show that prohibitions established in patent law of patents on plant and animal varieties and essentially biological processes i.e. conventional methods of plant and animal breeding (Art 53 (b) of the European Patent Convention, EPC) have been systematically eroded.

It appears that the EPO have in fact intentionally created an unprecedented situation full of legal absurdities. 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. However, in essence, these patents cover plant varieties as well as products and processes of essentially biological processes for breeding. Such patents have in fact already been granted. The cases documented in this report clearly demonstrate the legal absurdities in the details and no matter how currently pending cases (such as patents on broccoli and tomatoes, G2/12 and G2/13) are decided, it is highly likely that this development will be continued.

These patents granted by the EPO promote market concentration, hamper competition, and serve to promote unjust monopoly rights. Such patents have nothing to do with the traditional understanding of patent law, or with giving fair rewards and incentives for innovation and inventions. Based largely on trivial technical features, they are an abuse of patent law using it as a tool for misappropriation (in effect biopiracy) that turns agricultural resources needed for our daily food production into the so-called intellectual property of just a few big companies.

This development is not just a problem for specific markets or regions; it will ultimately endanger the agro-biodiversity of ecosystems and our adaptability in food production systems to react to the challenges of climate change. As a consequence, we are putting our global food security as well as regional food sovereignty at risk.

The report warns that decisions on whether patents on seeds, plants, animals are allowable cannot be left with the EPO, which is driven by its own vested interests. The EPO has systematically eroded the current prohibitions in patent law of Article 53(b) EPC in favour of those companies receiving the revenues from patented products and institutions that profit from granting patents. These interest groups in the patent industry have been a main driving force in directing the patent system away from being an instrument to promote innovation to a system that allows the misappropriation of biological resources needed to produce our daily food.

Maintaining and safeguarding free access to material needed for plant and animal breeding and agricultural production has to become a political priority. Any measures taken must primarily comply with the needs of farmers, traditional breeders and consumers and not with the interests of the 'patent industry'.

The key point is that patents on the resources needed for our daily lives can only be stopped by political decision-making. There are two steps that have to be taken:

- firstly, securing a vote by the contracting states of the European Patent Organisation (EPOrg) to ensure that the interpretation of the EPC is brought in line with a recent European Parliament resolution stating that generally patents on conventional breeding cannot be granted;
- and secondly, starting the process to change European patent laws to exclude patents on genetic resources, on plants and animals.

A further point is to ensure that current negotiations on the free trade agreements between the EU and Canada (CETA) and the US (TTIP) do not negate any possibility of Europe and the EU enforcing prohibitions in patent law in the future.

1. A brief outline of the problem

Products or processes can be patentable if they fulfill 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. Patents were originally developed for chemicals and mechanical products.

At present, an increasing number of European patent applications are being filed on plants and animals. Around 2400 patents on plants have already been granted – most of them covering genetic engineering. At the same time there is a steady increase in the number of patent applications being filed for conventional breeding. Around 1000 such applications have been filed and around 120 patents have been granted.

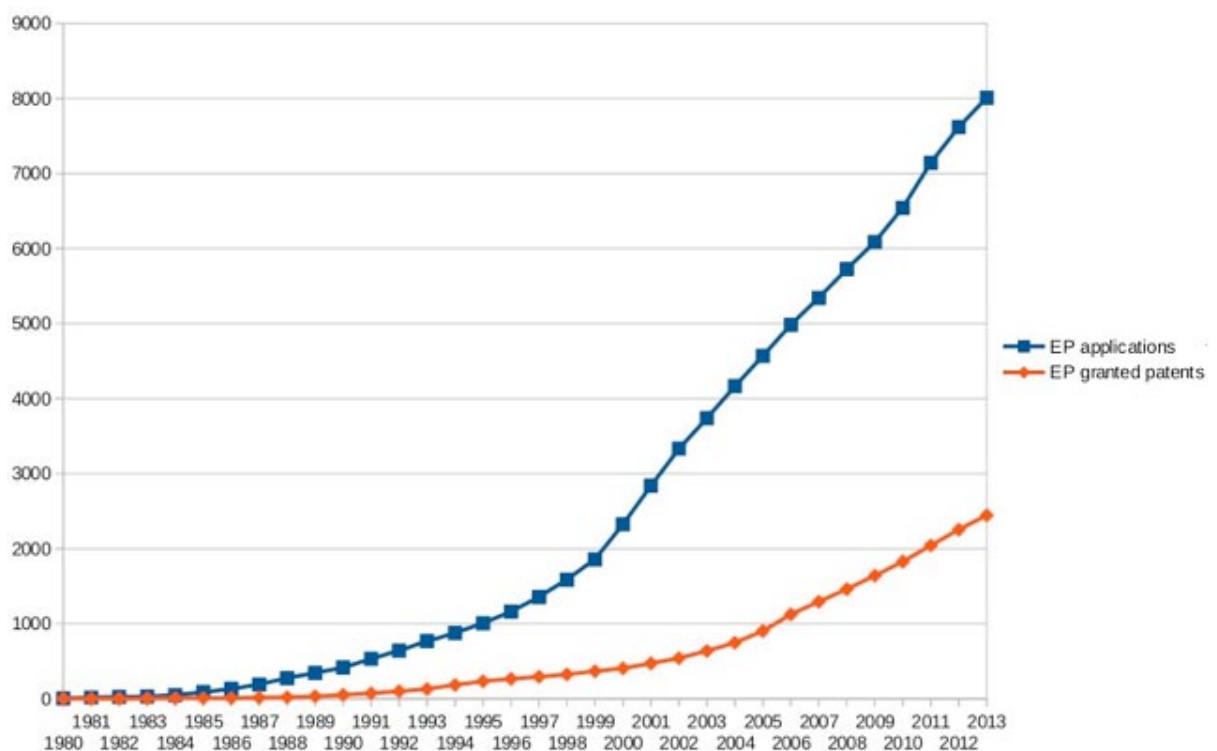


Figure 1: Number of patent applications and patents granted on plants at the European Patent Office in Munich (accumulated) Research according to official classifications (IPC A01H or C12N001582).

The scope of many of the patents is extremely broad and very often covers the whole food chain from production to consumption. These patents are an abuse of patent law designed to take control of resources needed for our daily lives. In particular, the activities of Monsanto, the biggest multinational biotechnology company and number one in the international seed market, are especially concerning: Monsanto has bought up, amongst others, the large vegetable breeders Seminis and De Ruiter and now has a very dominant position in seed markets for cotton, maize and soybeans. According to ETC-Group (2011), the three biggest companies Monsanto, Dupont and Syngenta control around 50 percent of the global proprietary seed market. They are the ones who will make the decisions on which plants will be bred, grown and harvested in future, and how much they will cost.



Figure 2: Patented food products that are already on the market.
For example, patented broccoli introduced in the UK as “Beneforte”
by Monsanto in 2011.

Patents on plants and animals can substantially restrict or hamper access to biological resources needed in plant breeding as well as hinder the process of innovation in breeding and impede the farmer’s activity and freedom of choice. This development is already impacting many stakeholders. These include traditional breeders, farmers who save, multiply or even breed their own seeds, developing countries that might be forced to allow patents on seeds, vegetable growers who become dependent on just a very few companies, organic producers looking for certified seeds, consumers, food producers and retailers who find that prices and choice in food products is being decided by companies such as Monsanto.

In general, these patents foster market concentration, hamper competition, and serve to promote unjust monopoly rights. Such patents have nothing to do with the traditional understanding of patent law, or with giving fair rewards and incentives for innovation and inventions. Based largely on trivial technical features, such patents actually abuse patent law, using it as a tool of misappropriation (in effect biopiracy) that turns agricultural resources needed for daily food production into the so-called intellectual property of some big companies. If the current trend is not halted, companies such as Monsanto, DuPont and Syngenta will be increasingly in a position to decide what is grown and harvested and served as food in Europe and other regions.

Furthermore, agro-biodiversity will decline if only a few companies are able to determine which patented super seeds should be grown in the fields. 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 our adaptability in 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. Overview on patent industry and the legal framework

The patent system has evolved over the years into what is now essentially a “closed shop”, governed by interest groups, vested commercial interests and mostly without any institutional representation of broader civil society.

2.1 The European Patent Office

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 1973¹.

According to the text of the EPC, patents on plants and animals are mostly excluded 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.”

In Europe, commercially traded seeds have to fulfil the requirements of plant variety registration, so the wording of this article should not mean anything other than a general prohibition of patents on seeds. However, as shown below, current EPO practice has completely eroded the prohibition of patents on seeds as well as the prohibition of patents on essentially biological processes for breeding.

The European Patent Organisation currently has 38 contracting states, comprising all the member states of the European Union together with Albania, Croatia, 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 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 Implementation Regulation.

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.

¹ <http://www.epo.org/about-us/organisation/foundation.html>

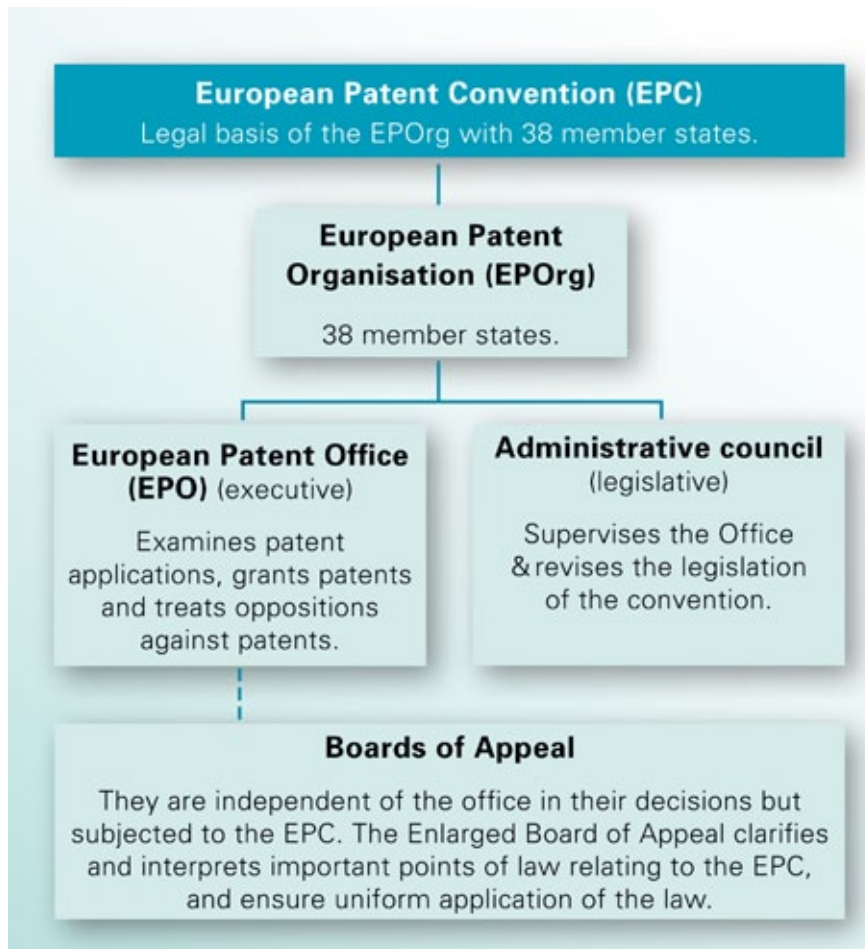


Figure 3: Structure of European Patent Organisation, EPOrg (source: Lebrecht & Meienberg, 2014)

The two Boards of Appeal are supposedly, at least partially, independent of the EPO in their decisions. But at the same time, 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 earns money by granting and examining patents and its budget (2014: 2 Billion €)² is mostly based on fees from patent holders (revenue from patent and procedural fees in 2013: 1,5 Billion €³). Consequently, the patent office has its own vested interest in receiving applications and granting patents. Industry (patent applicants) and the EPO have common interests. 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.

² [http://documents.epo.org/projects/babylon/eponet.nsf/o/125011cc1d9b8995c1257c92004b0728/\\$FILE/epo_facts_and_figures_2014_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/o/125011cc1d9b8995c1257c92004b0728/$FILE/epo_facts_and_figures_2014_en.pdf)

³ [http://documents.epo.org/projects/babylon/eponet.nsf/o/094DF1067B07003EC1257D040040A402/\\$File/financial_statements_2013_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/o/094DF1067B07003EC1257D040040A402/$File/financial_statements_2013_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 take part in the meetings:

- The contracting states of the EPOrg are represented by two delegates from each country. The representatives are mostly from the national patent offices or are legally qualified staff members of national authorities. As such the representatives can hardly be seen as an effective political control of the EPO – rather they are simply part of the ‚patent system‘. However, they are bound to the mandates of their governments – which can take control of political guidance if the contracting states request it.
- 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 BUSINESSSEUROPE and the Institute of Professional Representatives at the European Patent Office (epi) .
- BUSINESSSEUROPE is an umbrella organisation for national business federations and industry in 35 countries⁴.
- The Institute of Professional Representatives at the European Patent Office (epi) represents the European patent attorneys⁵. There are nearly 4000 registered European Patent Attorneys in Germany, and more than 2000 in UK⁶. 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 participants of the Administrative Council meetings 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 political control and certainly no public participation. In its decisions, the EPO insists that the consideration of the economic impacts of patents is not within its remit. But a closer look reveals that the EPO is driven by nothing other than its own economic interests and its affiliated patent industry.

4 <http://www.busesseurope.eu/content/default.asp?PageID=600>

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

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

2.2 The European Union, WIPO, TRIPs and TTIP

There are some other relevant international regulations and players in the patent industry.

The European Patent Directive 98/44

The most significant of these is an EU Directive (Legal Protection of Biotechnological Inventions 98/44 EC)⁷ that was adopted by the EU Parliament and EU member states in 1998. This directive was debated for about 20 years before it was finally adopted after heavy lobbying by industry. In some of its provisions the text of the Directive even goes beyond provisions in US patent law. For example, in Article 3 (2) it explicitly allows patents on discoveries if they are enabled by technical tools:

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

Although the EPO is not part of the EU, the Directive became part of the Implementation Regulation of the European Patent Convention in a vote taken by the Administrative Council in 1999. The relevant rules of the Implementation Regulation 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 plants and animals that are not confined to a particular plant or animal variety (see chapter 3).
- Article 2, 1 (b) of the Directive which became Rule 26 (5) of the EPC. It deals with the definition of essentially biological breeding methods (see chapter 3).

Both industry and the EPO considered the EU Patent Directive to be a major breakthrough for industry because it allows patents on plants and animals (Article 4). However, there are differing interpretations of its wording. The European Parliament, which adopted the Directive in 1998, requires that the prohibitions are much more strictly interpreted than is currently the case in EPO practice (see chapter 7).

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 system”⁸ that is meant to ensure supranational protection in 25 Member States of the EU. For the first time there will be a European patent court, the so-called “Unified Patent Court”⁹.

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 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.

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

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

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

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.

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)¹⁰ 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)¹¹ 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)¹².

In 2013, the negotiations started on the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US¹³. Intellectual property (IP) rights and patents are part of the package under negotiation. According to some informed sources, patents on software and business methods are on the wish list of the US delegation. Such patents (for example, to use a computer mouse click for running online-business) cannot be granted in Europe, because they are not regarded as being 'inventions'. If the US is successful within the TTIP, this could have huge implications for patents in relation to farming and breeding.

The consequences of free trade agreements such as TTIP are also relevant for future of patent law: if, for example, the EU prohibited patents on life after the TTIP comes into force, this could be considered a violation of the protection of investments of US companies.

¹⁰ <http://www.wipo.int/portal/en/index.html>

¹¹ http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

¹² http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

¹³ <http://ec.europa.eu/trade/policy/in-focus/ttip/>

3. Patents on plants and animals: current status and legal problems

In Europe, patenting plants and animals became a major phenomenon in the 1980s and 1990s as the first genetically engineered organisms were created. From the beginning this was a highly controversial issue. The granting of such patents was stopped in 1995 due to an opposition filed by Greenpeace against a patent on genetically engineered plants (Decision T356/93, EP 242236). The decision was based on the text of the European Patent Convention (EPC) which at that time and still does (!) exclude patents on plant and animal varieties as well as on essentially biological processes for breeding (see chapter 2). Since patents on genetically engineered plants also cover plant varieties, the EPO decided to stop granting such patents.

3.1 How the prohibition of patents on plant varieties became meaningless

In 1998/1999, two decisions were made in order to overcome the existing legal barriers and to serve the interests of industry. The decisions brought about a change, not in the law but in a different interpretation of the existing EPC. The Enlarged Board of Appeal of the EPO made a fundamental decision (G1/98) that patents not directed to specific plant or animal varieties, but to more general claim plants and animals, could be granted.

The EU Commission proposed the same interpretation of patent law at the same time, and it was eventually adopted as the text of the EU patent directive (“Legal Protection of Biotechnological Inventions”, 98/44 EC). As mentioned, this directive became part of the Implementation Regulation of the EPC – even though the EPO is not subject to EU legislation.

The wording of the EU Directive (Article 4,2) and the similar Rule 27 of the Implementation Regulation of the EPC reads as follows:

“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.”

A diagram presented by a representative of the EPO in a conference in 2011 shows the effect that this new interpretation had (see figure 4): 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 with relevant characteristics (higher content in vitamins), such as apples and tomatoes. 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.

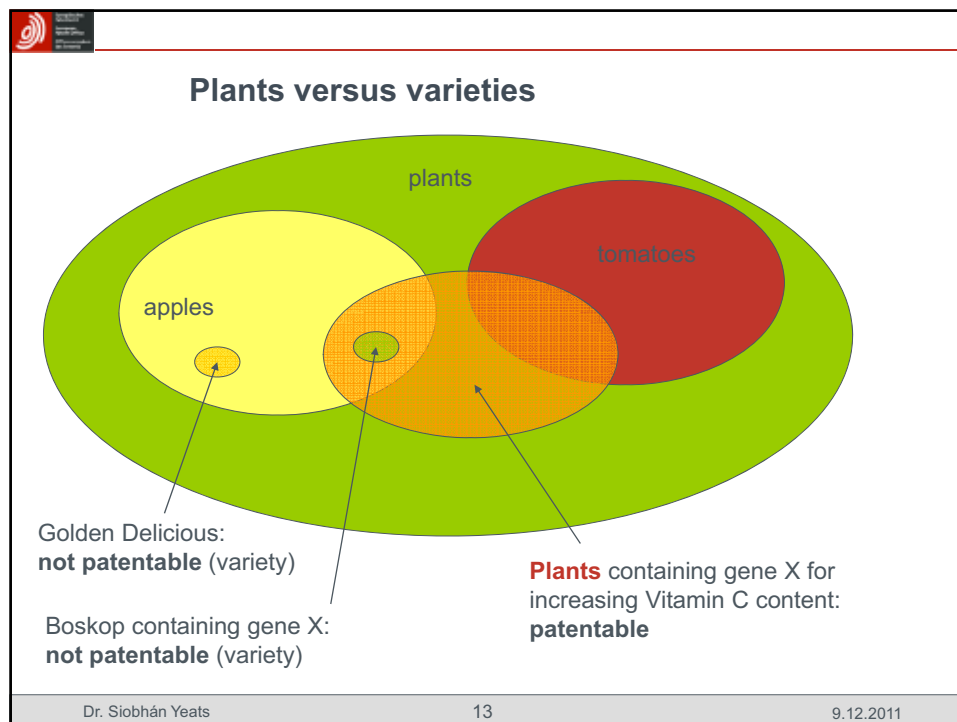


Figure 4: This slide shows how the European Patent Office currently interprets the prohibition of patents on plant varieties. While it is not possible to patent a defined variety of apples with a higher content in Vitamin C, it is possible to grant a general claim on plants with an elevated content of vitamins as an invention. Consequently, all the apple varieties of interest are included in the scope of the patent and become de facto patentable. (Source: EPO, 2011)

3.2 How the prohibition of patents on essentially biological processes was eroded

In 2010, a second fundamental decision was made on the patentability of plants and animals. The EPO Enlarged Board of Appeal gave an interpretation of “essentially biological processes” used for breeding plants and animals in decisions relating to both the G2/07 referral of the patent on broccoli (EP 1069819) and the G1/08 (EP 1211926) referral of the patent on tomatoes. Both patents are on conventional plant breeding and cover the process for breeding as well as the plants, the seeds and the fruits (the food).

The decision-making concerns the second part of Article 53 (b), EPC (“European patents shall not be granted in respect of (...) essentially biological processes for the production of plants or animals”); In this context, the Article 2,1 (b) of the EU patent directive 98/44 gives an interpretation which reads (similarly to Rule 26,5, EPC) as follows:

“A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.”

In the G2/07 and G1/08 cases a decision was made that processes based on crossing and subsequent selection cannot be patented. The first paragraph of the decision reads:

“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.”

This decision lacks legal clarity and opens up new questions:

- The decision only deals with processes – what about products produced by these processes (such as seed, plants and fruits)?
- What about claims on breeding processes that are just based on the selection of plants or animals before crossing?
- What about processes that include additional steps such as mutagenesis?
- What about methods such as vegetative reproduction?

After the G2/07 and G1/08 decisions had been made by the Enlarged Board of Appeal, the EPO still continued (until September 2013) to grant patents on products such as plants, seeds and fruits derived from conventional breeding. The only change that was made was to delete claims from the patents that were directed at the process of breeding (see chapter 4). Currently patents on breeding processes such as selection before crossing and propagation, which are not a combination of crossing and subsequent selection, are still considered to be patentable. The same is true for processes and plants resulting from mutation breeding (random mutagenesis). Patents are even being granted on processes for crossing and selection on the basis of cleverly worded claims (see below).

Consequently, - even after the G2/07 and G1/08 decisions - the prohibition of patents on essentially biological processes continues to be eroded.

The way in which the EPO deals with the provisions of Art 53 (b) EPC is paving the way for companies and patent attorneys to easily circumvent the prohibitions. The easiest way is to claim specific characteristics of a plant (or animal) by, for example, describing its genome, its compounds or agronomic features and formulate the claims to include all plant or animal species and all processes that could be used in theory (including genetic engineering) to produce a plant with the characteristics as described. The broader the claim (all plants, all processes) is, the higher the likelihood that the patent will be granted, including all relevant products. 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. However, in essence, these patents will cover both plant varieties and essentially biological breeding. In chapter 4 of this report we cite several cases to exemplify this kind of real and intended legal absurdity.

Number decision	question	outcome
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 process 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?	Still pending

Table 1: Overview of some decisions made by the Boards of Appeal at the EPO concerning patents on plants and animals

4. Patents granted on plants and animals

Around 2400 patents on plants and 1400 patents on animals have been granted in Europe since the 1980s. More than 7500 patent applications on plants and around 5000 patents on animals are pending. The EPO has already granted more than 120 patents on conventional breeding and around another 1000 patent applications in this field are pending.

The following section contains an overview of patents granted by the EPO in 2013 and early 2014. The patents granted on plants and animals in 2013 show that the EPO is systematically eroding the exceptions from patentability as described in 53 (b), EPC. There are several examples showing that patents that have been granted violate the prohibition in regard to plant varieties and essentially biological processes for breeding.

4.1 Overview

Patents granted in 2013

Around 200 patents on plants (including plants as well as processes for breeding) were granted in 2013. Our research shows that at least 25 of the patents concern conventional breeding (in some or all of their claims – see table 2 for overview).

Around 70 patents were granted on animals in 2013, most of them on laboratory animals. Some of the patents granted concern farm animal breeding, with some covering the selection of animals with specific meat quality.

After public protests in September 2013, the EPO put most of the pending patent applications on conventional breeding on hold, in effect a moratorium of patents on plants derived from processes of crossing and selection of whole genomes. Some of the patents about to be granted were stopped at last minute. Other patents such as those on selection of plants or mutagenesis can still be granted. Nevertheless, without this moratorium, that might end soon, many more patents would have been granted on conventional breeding in 2013.

Patent applications in 2013

In 2013, around 400 - 500 new applications for patents on plant breeding (plants and processes for breeding) were registered. According to our own research, around 130 of these (in some or in all of their claims) were for conventional breeding. As far as animals were concerned there were more than 100 new applications pending some of which were for conventional animal breeding.

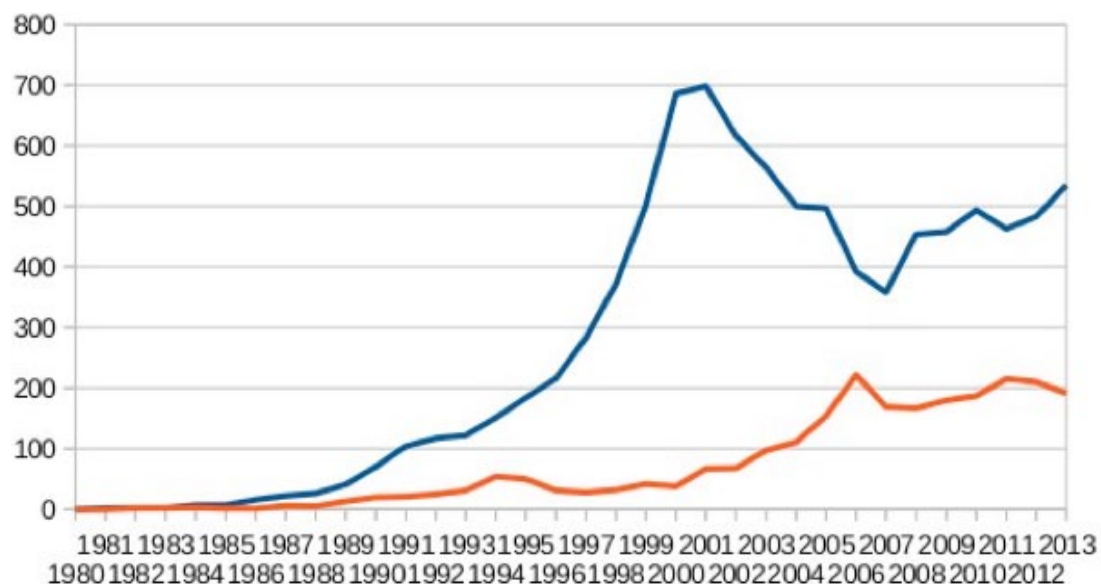


Figure 5: Patents on plants - number of patent applications on all plants under PCT/WIPO (WO) as well as of patents on plants granted by the EPO (lower line) per year. Research according to official classifications (IPC A01H or C12N001582).

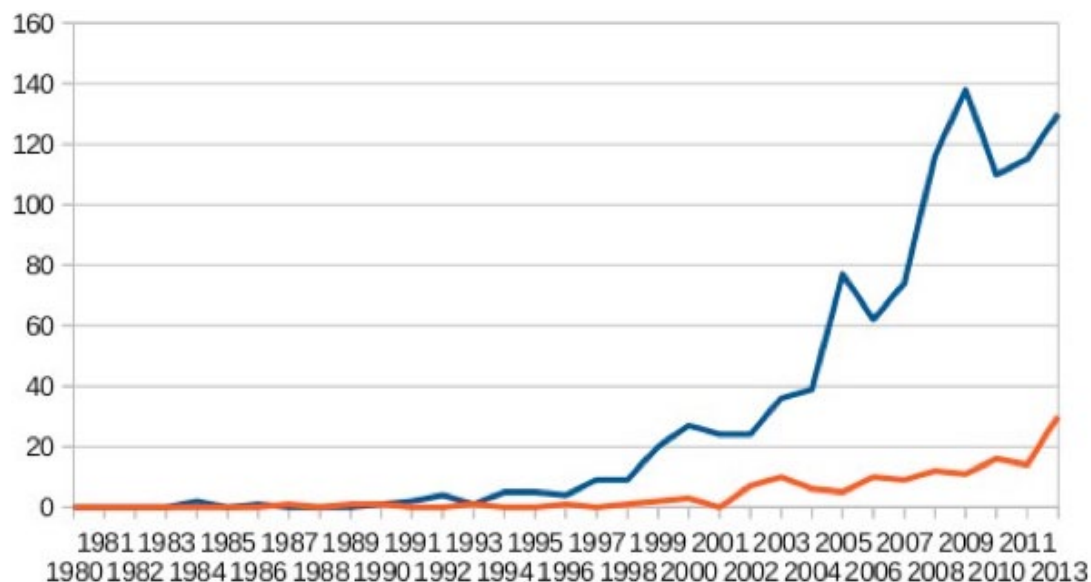


Figure 6: Number of patent applications (EP) and patents granted concerning conventional plant breeding (EP B – lower line) by the EPO per year (own research).

4.2 Case studies: recently granted patents on plants

Wild pepper

In May 2013, the European Patent Office (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 fact that this patent has been granted shows that the EPO still believes that products derived from essentially biological breeding are patentable. Further it shows that all steps of breeding and use of the plants, including selection, growing of the plants and harvesting the seeds, are regarded as being patentable in addition to all relevant plant varieties. This makes the interpretation of the prohibition of patents on essentially biological breeding meaningless. The patent granted to Syngenta was opposed in February 2014 by “No Patents on Seeds!” together with a coalition of 34 NGOs, including farmers’ organisations and breeders from 28 countries.

Severed broccoli

In June 2013, Seminis, a company owned by Monsanto, was granted patent EP 1597965 on broccoli. The patent claims plants derived from conventional breeding grown in such a way as to make mechanical harvesting easier. The patent covers the plants, the seeds and the “severed broccoli head”. 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. It was decided that the method of breeding was not patentable, but nevertheless the products derived thereof were regarded as technical inventions. In fact, the broccoli as described in the patent is simply a plant variety. The same patented characteristic in the US is even explicitly called a plant variety (in the US, patents on plant varieties are allowed). In May 2014, an opposition was filed by “No Patents on Seeds!”.

Selection of soybeans

In February 2014, the European Patent Office in Munich (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. The patent was granted on the method of selection before crossing takes place, which – according to the interpretation of the EPO (G1/07) – is not an essentially biological method for breeding, because it does not include sexual crossing. As a result, Monsanto gets what it wants: a broad monopoly on the most basic prerequisite in plant breeding, the usage of natural genetic variety.

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 (EP1973396). The patent itself claims a trivial process of screening (“creating a wound surface on the plants or plant parts to be screened”) for relevant phenotypes. It further covers plants, progenies, parts of the plant, the seed and the food. All relevant plant varieties are also within the scope of the patent. In this case the prohibition of granting patents on essentially biological breeding was circumvented by simply avoiding claims that are directed to crossing and selection. Instead, a trivial method for selecting plants (cutting them and observing, called screening) was claimed as ‘invention’. 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.

Tomato resistant to fungal disease

In August 2013, a patent was granted to Monsanto/ De Ruiter on tomatoes with resistance to botrytis, which is a fungal disease (EP1812575). The original plants were received from the international gene bank in Gatersleben (Germany). The patent covers relevant markers for selection of the plants as well as the plants, seeds and fruits. All relevant plant varieties are also within the scope of the patent. As the description of the patent shows, the relevant plants were produced simply by crossing and selection. But claim 1 of the patent reads very generally “transfer of said nucleic acid is performed by crossing, by transformation, by protoplast fusion...”. This wording was used as a simple trick to hide that it is just crossing and selection. There are other, similar cases such as EP 1874935 (DuPont) which uses the word “introgressing” instead. Thus one could say, granting of these patents is mostly based on fraud by industry, supported by the EPO.

Random mutagenesis in sunflowers

In April 2013, the Spanish institution Consejo Superior de Investigaciones Cientificas received a patent on sunflower plants and sunflower oil that are derived from random mutagenesis by using radiation (EP0965631). This process is stochastic, its result depending on the genetic background of the plants and is subject to the plants’ own gene regulation. This technique is neither new nor inventive. There are good reasons to question whether a breeding method can be considered as ‘traditional’ if it is triggered by chemical compounds or radiation. However, in the context of patent law and also in the light of EU Directive 2001/18, the level of technical interaction with the plant material is a much more useful criterion than simply calling something ‘traditional’ or ‘non-traditional’. Mutagenesis only involves a low level of technicality as mutagenesis means interacting in non-targeted way with the whole cells and the whole genomes. The difference becomes evident by comparison with genetic engineering. Genetic engineering involves the insertion of isolated DNA, by invading the cells using technical means and acting directly at the DNA level. Thus, methods such as random mutagenesis fall within the prohibition of Art 53 (b) EPC and are non-patentable because they are essentially biological, even though it might not be considered to be ‘traditional’. However, as this case shows, and given the G2/07decision, use of mutations in breeding is regarded as being patentable by the EPO. In addition, patents such as EP 0965631 are also a problem in regard to the prohibition of patents on plant varieties.

Table 2: overview of some patents granted by the EPO in 2013 on conventional breeding

EP number	Company	Species	breeding method	claims
EP 1786901	Dow AgroSciences	cereal plants	mutagenised 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	triploid breeding	watermelon
EP 2114125	University of Kansas	sorghum	marker selection, genetic engineering	plants, seeds, DNA

EP num-ber	Company	Species	breeding method	claims
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 Ruiter Seeds / Monsanto	tomato	marker selection, crossing, introgression	plants, seeds, fruits, crossing ("transfer of nucleic acid")

4.3 Case studies: patents recently granted on animals

In 2013, several patents were granted on animal breeding, especially on methods to select animals before and after crossing. Amongst these are marker selection for mastitis resistance in cattle (EP 2069531), genetic markers for meat colour and relevant mutations (EP2331710) as well as markers for tenderness of bovine meat (EP2061902).

There are no claims on animals in these patents. However, depending on the wording of the claims, such patents can be used to control further breeding if the animals in following generations have the genetic conditions as described in the patent. Thus, this type of patent can interfere with conventional breeding in animals and can, for example, be used to stop farmers from further breeding dairy cows. Currently, an appeal against a patent on selection for the breeding of dairy cows by marker DNA (EP 1330 552 B1) is pending at the EPO.

Another case was decided in 2014 in an opposition procedure, this was patent EP 1263521 (Ovasort, UK), which is about sex selection in animals. The EPO decided that a particular claim directed to the production of embryos was assumed to be a process based on crossing and selection, and therefore not patentable. For procedural reasons, the EPO revoked the whole patent, but explicitly stated that in general it is possible to grant claims that are directed to animal sperm cells (breeding material) and the selection of the animals. As the EPO states in its written decision regarding this patent:

"A method directed to technical steps taking place before the breeding step and not including the breeding step per se does not fall under the prohibition of Art 53 (b) EPC."

5. The impact of patents on seeds

The whole of the food chain (breeders, farmers, processors, retailers, consumers) could be affected if patents are granted on seeds, plants, fruits and derived products. Such claims are part of several patents that have been applied for and granted in Europe. The higher the number of such patents that are filed for and granted, the higher their impact will be on the market. So far, the most relevant concern is the concentration of the seed market, globally and in the EU as described in following paragraphs in more detail.

- › Several sectors have already felt the impact of this development:
- › Traditional breeders, relying on the system of breeders' exemption under the plant variety protection system that allows usage of existing seeds for further breeding (see below);
- › Farmers who save, multiply or even breed their own seeds;
- › Developing countries that might be forced by bilateral trade agreements to allow patents on seeds to same extent as in Europe and the US;
- › Vegetable growers who find themselves highly dependent on just a few companies;
- › Organic producers who are dependent on the availability of certified seeds;
- › Energy producers using products from plants;
- › Consumers who find that even regional varieties no longer have a true diversity of food quality;
- › Retailers who find their prices and revenues will be decided by companies such as Monsanto.

It must be emphasised that many farmers in Europe are still breeders themselves. This applies especially to dairy farmers, but also to farmers who produce their own seeds. These farmers make use of the breeders' exemption in plant variety protection (PVP). However, they cannot use patented plants or animals for their purposes. In Europe, farmers can still use traditional seeds handed down through the generations to cultivate plants that are adapted to their local environment. Large biotech companies selecting plants with interesting native traits (such as drought or pest resistances) are using the very same genetic pool. If these kinds of plants are patented, farmers might no longer be able to use these local varieties. Furthermore, fields might be contaminated with pollen from plants with patented traits. While in Europe there are several regulations in patent laws stating that these cases cannot be regarded as an infringement of patent rights, legal uncertainty remains for countries that do not have such regulation in their patent law.

In general, if patents on conventionally bred plants and animals are allowed in Europe, farmers will have to face the same problems as, for example, US farmers who are targeted by private investigations on behalf of multinational companies to identify potential violations of their patents. If farmers are taken to court because of a violation of patent rights, they are confronted by expensive and highly qualified lawyers backing the position of industry. So who will defend the farmers if such patents are enforced?

An overview of some of the possible consequences is summarised in Figure 7, taken from a report (Lebrecht & Meienberg, 2014) on the pepper plant patent (EP2140023). In the following paragraphs there is an overview of some of the consequences for the seed market and farmers that are already evident.

Above and beyond this scenario, agro-biodiversity will decline if just a few companies are able to determine which patented super seeds should be grown in the fields. Agro-biodiversity is one of the most important preconditions for the future of breeding, environmentally-friendly agriculture and adaptability of our food production to changing conditions such as climate change. Seen from this perspective, seed monopolists will not only take control of our daily food but also endanger the future of ecosystems as well as global food security and regional food sovereignty.



REASONS AGAINST PATENTS ON SEEDS

Patents on seeds are unethical. They benefit multinational corporations at the expense of farmers and breeders. They hinder innovation, lead to decreasing agricultural biodiversity, and pose a risk to our food security.

> LIVING ORGANISMS CANNOT BE INVENTED // Plants and animals evolved over millions of years by natural selection. Various breeding methods allow us to manipulate this process. This means we can alter plant and animal varieties according to our wishes. However, we cannot invent them. A living organism cannot, also from an ethical point of view, be the intellectual property of a company.

> INCREASED MARKET CONCENTRATION // Granting such patents allows corporations to exclude their competitors from the market and thus further promotes market concentration in the seed sector. Small and intermediate companies will be displaced by large corporations because they have less financial means to file and force patent applications. This process is further accelerated by the fact that one patent can incorporate many varieties, or the other way around: One variety can be blocked by different patents. For example, there is a patent on lettuce that incorporates at least 158 different varieties.⁵

> CONTROL BY A FEW INTERNATIONAL CORPORATIONS // This means that the competition will be eliminated and only a few corporations will control the proprietary seed market and thus the basis of our food. Today, only 10 corporations own about 75 % of

the international seed market. The three largest, Monsanto, DuPont and Syngenta, control over 50 % of the market. In the case of peppers, only two international companies, Monsanto and Syngenta, own almost 60 % of all protected varieties in Europe.⁶

> INCREASED PRICES FOR FARMERS AND CONSUMERS // Through the monopolisation of the seed market, corporations are free to determine the prices for their seeds, at the expense of farmers, and ultimately, consumers.

> LESS INNOVATION // Contrary to the intended purpose, patents on seeds substantially hinder innovation. Breeders and farmers are not allowed to breed using patented varieties without the permission of the patent holder. If permission is obtained, a licence fee must be paid to the patent holder.

> LESS BIODIVERSITY // The diversity of agricultural varieties and wild crops are the main resources for breeders to develop new varieties. If access to this diversity is hindered, there will be less innovation. Less innovation leads to less new varieties there by decreasing biodiversity in agriculture and the choice for consumers.

> ENDANGERED FOOD SECURITY // Given reduced diversity, crops are less capable of adapting to diseases or changing environmental conditions (such as climate

change). Therefore, high agricultural biodiversity is essential for our food security.

> HUNTED FARMERS // Patent infringement can have severe consequences for farmers and breeders. If a farmer planted, saved or sold patented seeds, it does not matter whether he knowingly did so or not. For example, his own seeds may have been contaminated by patented seeds. Especially in the United States there are cases where farmers had to pay out-of-court fees of up to \$35 000 to

Monsanto to avoid criminal prosecution. Additionally, the farmers had to allow Monsanto to take field samples in subsequent years and they had to sign non-disclosure agreements. Other farmers who chose to fight and defend themselves in court were subjected to long and costly legal processes. Not only farmers also breeders and even companies that sell vegetables can be prosecuted.

Figure7:

Some of the consequences
of patents on plants

(Source: Lebrecht & Meienberg, 2014)

5.1 Global overview of concentration in the seed market

In 2013, the European Commission presented a report on the structure of the EU seed market. It also gives an overview of the situation on the global seed market (EU Commission, 2013a).

According to this overview, international seed market concentration has increased dramatically in recent years. While in 2009, the biggest three companies had a market share of around 35 percent, by 2012 this figure had risen to 45 percent. At the same time, the market share of Monsanto, which is the biggest seed company, increased from 17.4 to 21.8 percent. These figures show slightly lower percentages for market shares for the biggest seed corporations than the ones from ETC (2011 – see chapter 1), but do still in general confirm a worrying trend.

The figures presented by the Commission (EU Commission 2013a) were used for the chart in Figure 8, which shows changes in the global proprietary seed market from 1985-2012 (see also Meienberg & Lebrecht, 2014). The changes are mostly driven by agrochemical companies such as Monsanto and Dupont, that are buying up more and more seed companies (see Howard, 2009).

Patents are increasingly promoting this process of concentration and putting the largest seed companies in a dominant market position. By buying up other breeding companies, the multinationals are also acquiring more varieties and genetic material from the breeders' gene banks. If later on they bring their patented seeds on to the market, the genetic material the seeds contain will no longer be able to be freely accessed by other breeders as it is now under the plant variety protection (PVP) system.

PVP is in its own way an intellectual property right that gives breeders an exclusive right to the production and sale of new varieties over a period of 25 or 30 years. The protected varieties can be used by other breeders for the development of other new varieties (breeders' exemption). Patents, however, can block or hinder access to seeds for further breeding and commercialisation.

Therefore, if patents on seeds are allowed, there will be a much greater effect on the concentration process than under PVP law. Acquisition of breeding companies, of breeding material and use of patent monopolies are all having a synergistic effect on the process. In the end, as competition declines farmers, growers and consumers will be increasingly dependent on multinational corporations.

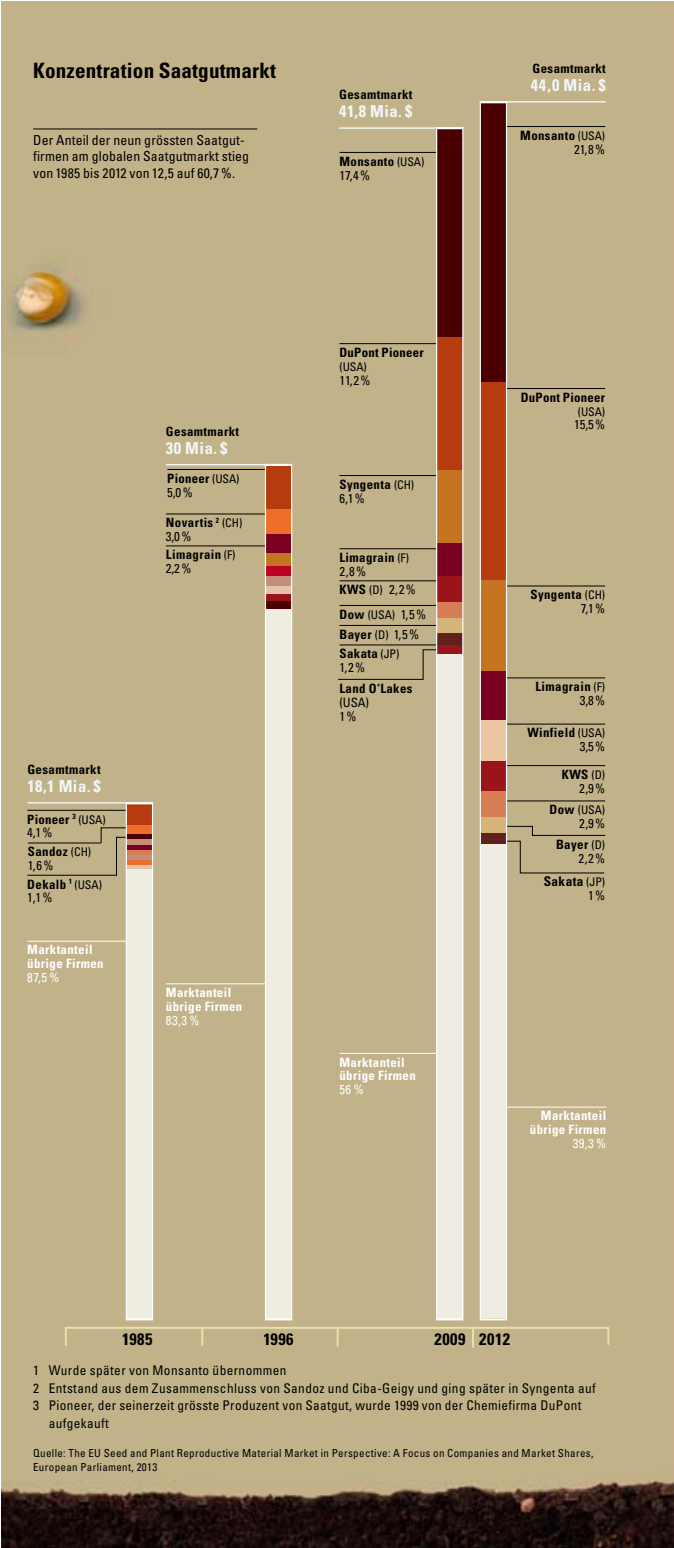
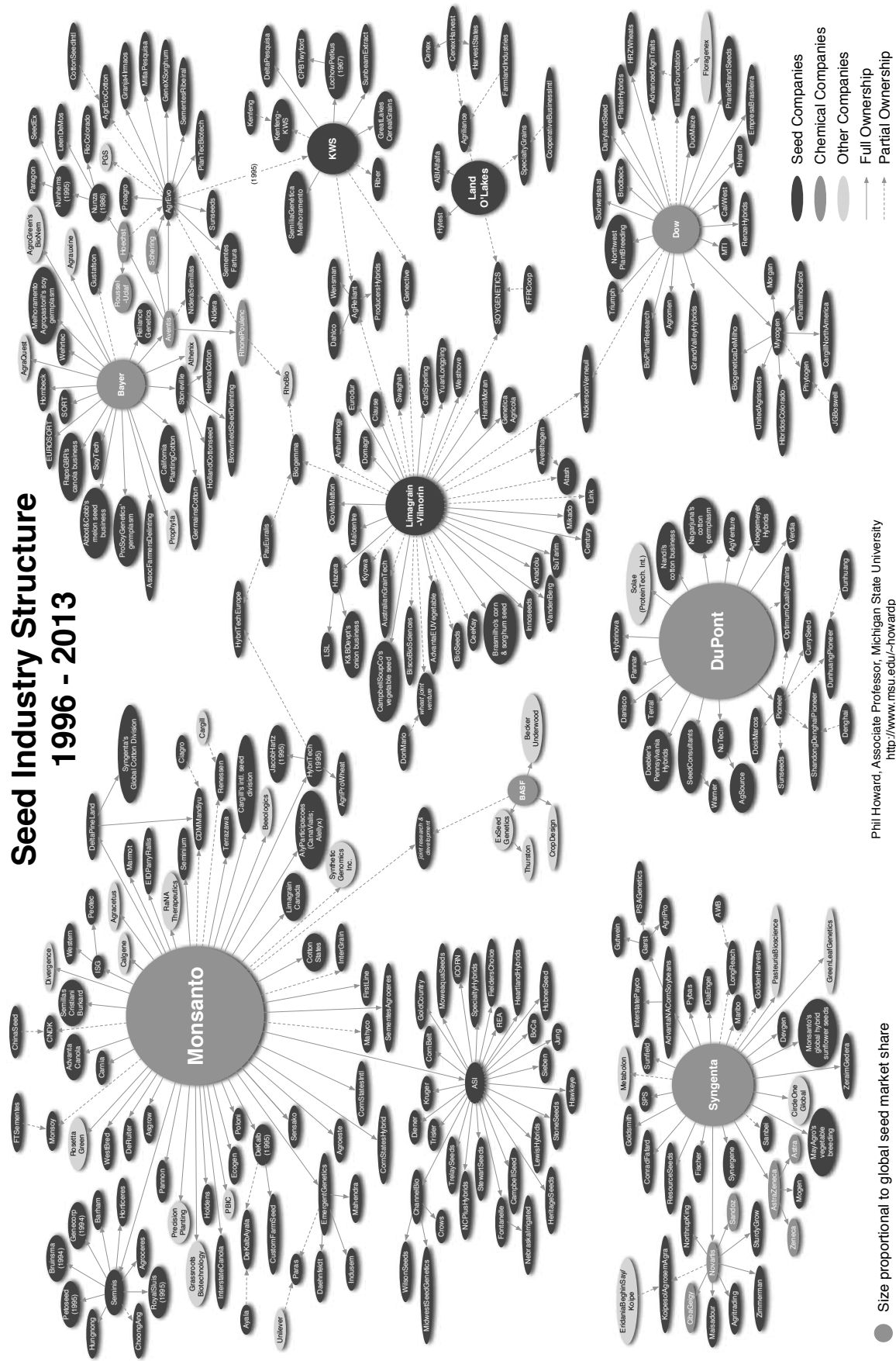


Figure 8:
Concentration in the seed market.
(Source: EU Commission 2013a
and Meienberg & Lebrecht, 2014)

Seed Industry Structure 1996 - 2013



Phil Howard, Associate Professor, Michigan State University
<http://www.msu.edu/~howardp>

Figure 9: Global overview of market concentration driven by acquisitions made by Monsanto, Dupont, Syngenta and other corporations in recent years (source: Howard, 2013¹⁴)

DMarket concentration is not only happening in the markets for cereal crops such as maize and soybeans but also in the vegetable market. According to the EU Commission (2013a), which uses the figures based on information from Vilmorin, just six companies control more than 50 percent of the global vegetable seed-market.

Company	Country	Turnover (vegetable seeds, in € million)	Estimated global market share	Cumulated market shares
MONSANTO VILMORIN (Limagrain Group)	United States	655	14%	14%
	France	527	11%	25%
SYNGENTA	Switzerland	468	10%	35%
NUNHEMS (Bayer Crop Science)	Germany	299	6%	41%
RIJK ZWAAN	The Netherlands	229	5%	46%
SAKATA	Japan	220	5%	51%
Other companies*		2400		
Total world market for vegetable seeds*		4800		

Source: Elaboration by EP Policy Department B, based on data from VILMORIN, Annual report 2012. *: "Other companies" and "Total world market for vegetable seeds" were estimated based on information from VILMORIN.

Figure 10: Six companies control more than 50 percent of the global market for vegetable seeds. (Source: EU Commission, 2013a).

Monsanto's dominant role in the vegetable seed market is due to their acquisition of Seminis and De Ruiter, both leading vegetable breeders. According to Monsanto's annual reports¹⁵, the turnover for seeds has grown steadily in recent years. As shown in Figure 11, net sales for maize (corn) seeds have increased significantly, and there has also been an increase in sales for soybeans and vegetables.

15 Monsanto, Annual Reports, www.monsanto.com/investors/pages/archived-annual-reports.aspx

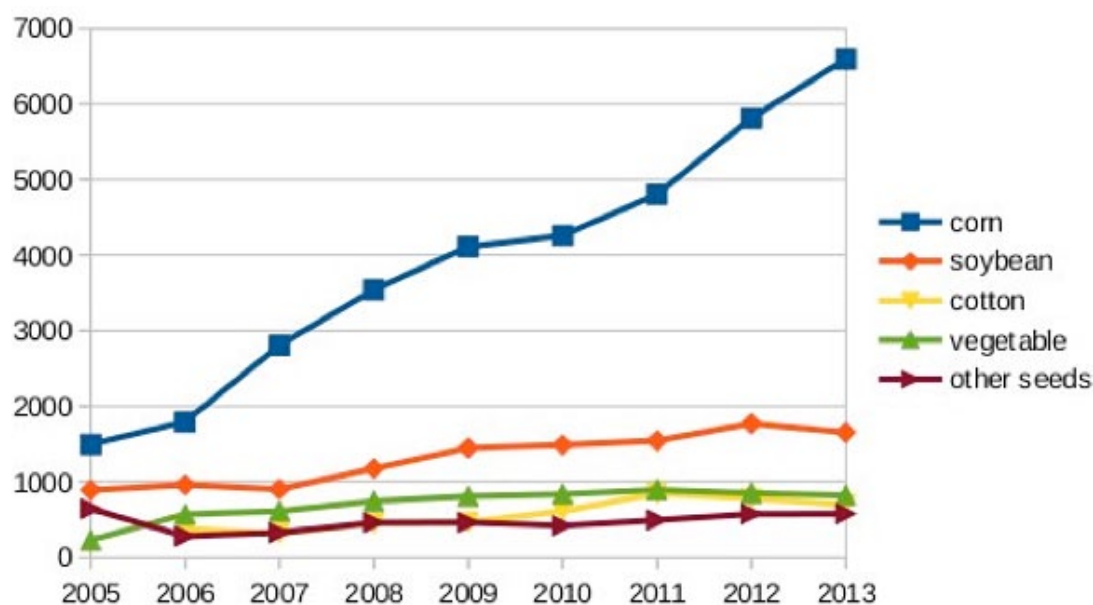


Figure 11: Net Sales (US Dollars in thousands) of Monsanto in the seed business, globally, per year. (Source: Monsanto annual reports; the figures for net sales of corn, soybean and cotton also include fees for traits of genetically engineered traits).

5.2 The situation in the US

The seed market in the US is more exposed to patents than in the EU. There are two reasons for this: (1) There is no exclusion in patent law regarding plant breeding. (2) Plants derived from genetic engineering play a much larger role in US agriculture. Thus, patenting and licensing of the genetically engineered traits (such as herbicide resistance) have had a major impact on breeding and agriculture.

There are several reports showing a high level of concentration in US seeds market for crop species such as maize (corn) and soybeans (for example, the Center for Food Safety & Save our Seeds, 2013). Recent figures can also be derived from seed company reports such as KWS (Germany)¹⁶. According to their figures, Monsanto and DuPont/Pioneer together have a market share of 70 percent in the US corn (maize) market¹⁷.

Monsanto and DuPont are also the number one companies when it comes to the number of relevant patents in the US. According to Pardey et al. (2013), the overall number of US utility plant patents granted from 2004-2008 was 1789, with Monsanto owning 640 (36 percent) and DuPont /Pioneer 516 (29 percent).

¹⁶ KWS has a cooperation with the French company, Limagrain, to sell seeds for corn producer in the US under the brand AgReliant.

¹⁷ https://www.kws.de/global/show_document.asp?id=aaaaaaaaaffxwn

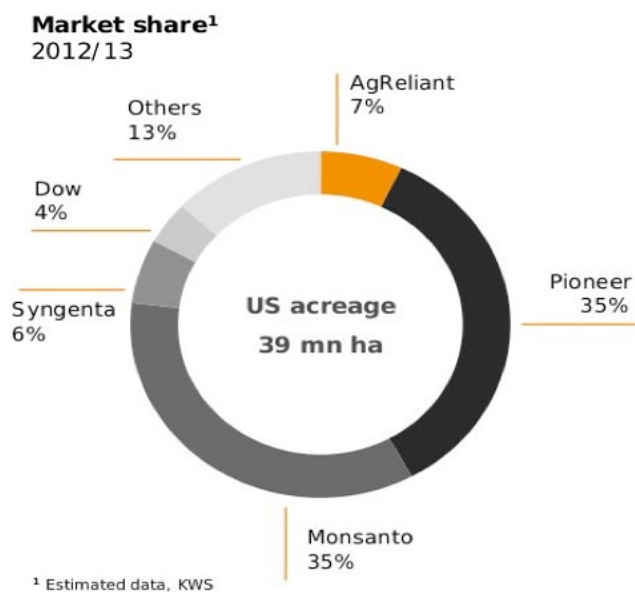


Figure 12:
Structure of US seed market for
corn (maize) (source: KWS)..

As a consequence of market concentration, the US seeds market is now suffering from a lack of competition and farmers have a much reduced choice (Hubbard, 2009). Open source seed initiatives (see Kloppenburg, 2014) are trying to raise public awareness, but doubts remain whether changes can be made in the near future.

Part of the overall financial impact on US farmers can be deduced from the official USDA data¹⁸. The following figures (based on these data) give an overview of the development in costs for seeds and chemicals, as well as for yields in the US for corn (maize), soybean and cotton. It clearly reveals soaring seed prices in all three crops without a corresponding increase in yields. US soybean and maize farmers can still survive because soaring demand for food, feed and agrofuels leads to higher prices for the harvest. Nevertheless, it is a situation determined by steadily increasing seed costs and a seed market without any real competition, in addition to stagnating yields – all in all, a frightening scenario for the future of US agriculture.

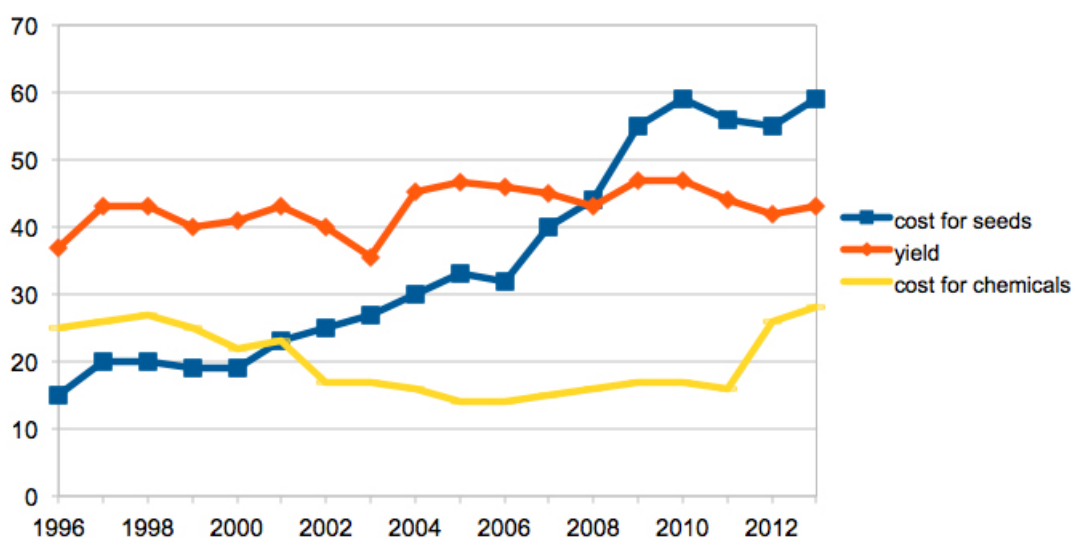


Figure 13: Development of costs for seeds (seed, US dollar per acre), costs for chemicals (chemicals, US dollar per acre) and yields (yield, bushel per acre) for soybean cultivation in the United States from 1996-2013 (source: USDA data)

¹⁸ <http://www.ers.usda.gov/Data/CostsAndReturns/testpick.htm>

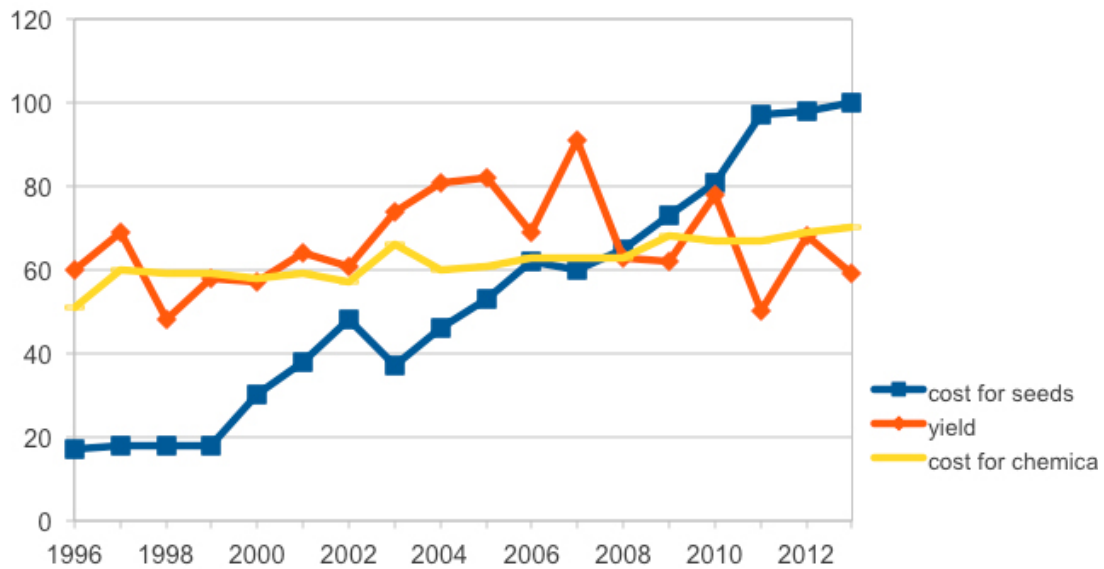


Figure 14: Development of costs for seeds (seed, US dollars per acre), costs for chemicals (chemicals, US dollars per acre) and yields (yield, pounds per acre, values equal to 10% of actual yields) for cotton cultivation in the United States from 1996 to 2013 (source: USDA data)

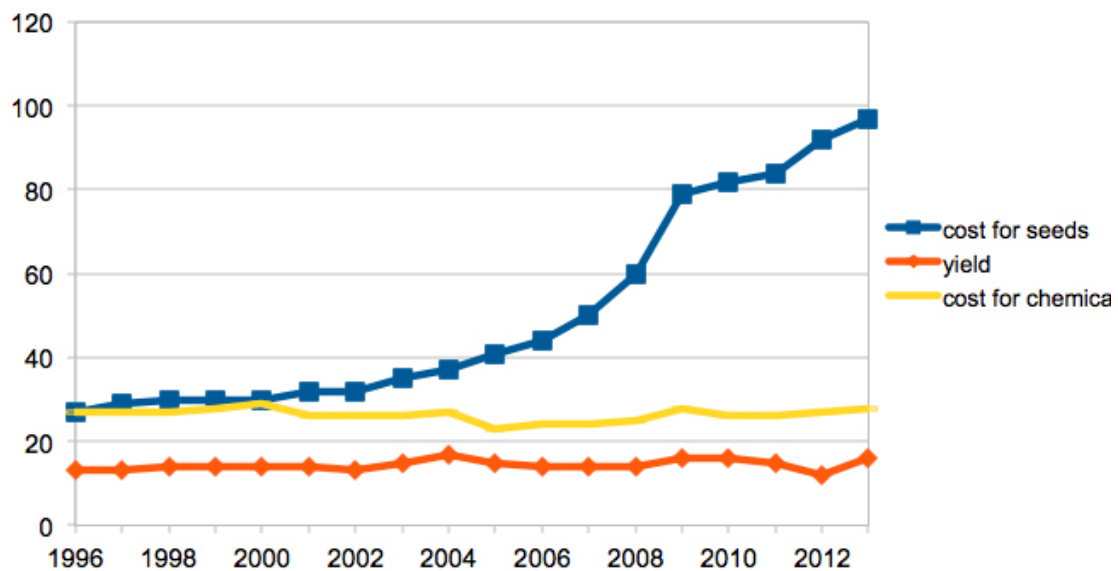


Figure 15: Development of costs for seeds (seed, US dollars per acre), costs for chemicals (chemicals, US dollars per acre) and yields (yield, bushel per acre, values equal to 10% of actual yields) for maize (corn) cultivation in the United States from 1996-2013 (source: USDA data)

5.3 Concentration in the seed market in Europe

The seed market in the EU is the third biggest seed market in the world with a volume of 7 billion Euros, representing 20 percent of the global proprietary seeds market (EU Commission, 2013a). Overall, Syngenta is the biggest company in the EU seeds market, while Monsanto is the leading company in seeds for oilseed rape and Dupont/Pioneer for maize (EU Commission 2013a).

Although there are officially 7000 companies in the breeding sector in the EU (EU Commission, 2013a), not many of them play a major role. As a report drawn up by the Greens in the EU Parliament explains, only five companies share 75 percent of the EU maize market (Mammana, 2013), and the same number of companies control 95 percent of the vegetables seeds market (see also EU Commission 2013b).

There is no doubt that although the seed giants are increasing their market share in the EU there is no full consensus amongst experts about the consequences for the EU market especially for the breeding sector. A study commissioned by the Dutch government (Kocsis et al., 2013) comes to the conclusion that the seed market for tomatoes and peppers is exposed to increased concentration but this would not automatically lead to a lack of competition.

This statement is not very convincing in regard to the overall development. It is true that the EU seed market still has a much higher degree of diversity than the US market. But this current situation cannot settle the existing concerns. According to the EU Commission (2013a), the differences between US and EU markets are largely influenced by the fact that the EU is still a conventional seed market, while crops with genetically engineered traits such as soybeans, maize and cotton have had a big impact in some sectors of the US agriculture. Indeed, licensing of patented traits of genetically engineered plants is an important factor in regard to competition, prices of seeds and the market power of agrochemical companies in the US. However, for several reasons, current differences between the US and EU might be erased in the near future:

- Acquisitions and mergers have already reached the conventional seed business in Europe. As mentioned, there is a very high level of concentration in the EU vegetable seed sector (EU Commission 2013b).
- The number of patents on conventional breeding are still relatively low compared to those in genetic engineering, but there has been a substantial increase in number of patent applications in this field since the year 2000 (see chapter 4).
- Even a low number of patents can create far-reaching dependencies in the breeding sector. For example, patented native traits (e.g. pest resistance) can be licensed in the same way as genetically engineered traits, and also have a similar impact on the market.

This licensing of traits in conventional breeding is a reality. In 2004, a patent was granted to Rijk Zwaan on lettuce derived from conventional breeding with resistance to aphids (EP 0921720). Because 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. Meanwhile the PINTO database¹⁹ established by European Seeds Association (ESA) has shown that

¹⁹ <http://pinto.azurewebsites.net/>

548 varieties registered in Europe contain elements of the licensed variety. This example 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 that are one of the driving factors in seed market concentration in the US.

There are other examples in the PINTO database showing that single patents on conventionally derived traits can simultaneously impact the breeding of many varieties. As table 3 shows, until May 2014 there were only around 20 patents listed in the database, but the number of varieties affected was nearly 800. It has to be noted that the Pinto Database is not complete because it is not supported by the whole of the breeding sector, as some companies, notably Dupont / Pioneer and Monsanto/ Seminis / De Ruiter are refusing to provide data.

It is likely that current differences in the seed market between US and EU will be eradicated in a short space of time if Europe continues to grant patents on conventional breeding. While the development is hard to predict in detail, there seems to be a high overall probability that the seed market in Europe will undergo further concentration with drastic impacts. A report from the University Wageningen clearly states (Louwaars, 2009) that:

“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 (...).”

Patent holder	Patent number	Patent title	Species	Varieties (number)
Bejo Zaden B.V.	NL1023179C	Brassica plants with high levels of antivaricogenic glucosinolates	Purple sprouting broccoli (Brassica oleracea L.)	5
	EP2645849	Plasmodiophora brassicae-resistant Brassica plant, seeds and plant parts thereof and methods for obtaining the same	Red cabbage (Brassica oleracea L.)	1
	EP2139311	Brassica oleracea plants with a resistance to Albugo candida	White cabbage (Brassica oleracea L.)	1
	EP2393349	Xanthomonas campestris pv. Campestris resistant Brassica plant and preparation thereof	White cabbage (Brassica oleracea L.)	4
Enza Zaden Beheer B.V.	EP1179089	Method for obtaining a plant with a long lasting resistance to a pathogen	Lettuce (Lactuca sativa L.)	158
Goldsmith Seeds Inc.	EP0740504	Phytophthora Resistance Gene Of Catharanthus And Its Use	Vinca (Catharanthus roseus)	8
Institute National de la Recherche Agronomique	EP0784424	Cytoplasmic male sterility system producing canola hybrids	Oilseed rape (Brassica napus)	24
	EP1198577	Mutant gene of the GRAS family and plants with reduced development containing said mutant gene	Oilseed rape (Brassica napus)	3
	EP1586235	Cytoplasmic male sterility system producing canola hybrids	Oilseed rape (Brassica napus)	27
	EP2179643	Method of Producing Double Low Restorer Lines of Brassica Napus Having a Good Agronomic Value	Oilseed rape (Brassica napus)	1
Limagrain Europe	EP2461666	Brassica plant for restoring fertility in an ogura cytoplasmic male-sterility system, method for producing same, and use of said plant	Oilseed rape (Brassica napus)	3
Nickerson Zwaan B.V.	EP1819217	Resistance to downy mildew of onion caused by the fungus peronospora destructor	Onion (Allium cepa)	1
Rijk Zwaan	EP0921720	Aphid resistance in composites	Lettuce (Lactuca sativa L.)	439
	EP0942643	Multileaf Lettuce	Lettuce (Lactuca sativa L.)	26
	EP2586294	Peronospora resistance in Spinacia oleracea	Spinach (Spinacia oleracea)	7
Semillas Fito, S. A.	EP2255006	Process for producing tomato plants with long-life characteristics	Tomato (Solanum lycopersicum)	3
Syngenta Participations AG	L525317 & EP2302	Clubroot Resistant Brassica Oleracea Plants	Brussels sprouts Cauliflower White cabbage	3 5 9
		Flower Pigmentation In Pelargonium Hortorum	Geraniums (Pelargonium hortorum)	1
		F. Oxysporum F.SP. Melonis Race 1,2 Resistant Melons	Melon (Cucumis melo)	5
		Novel cucurbita plants	Squash (zucchini - Cucurbita pepo)	9
	EP2121982 & EP2242850	Maize plants characterized by quantitative trait loci (QTL)	Maize (Zea mays)	25
Total number of varieties				757

Table 3: PINTO database on some patents granted in Europe and number of plant varieties concerned
(Source: <http://pinto.azurewebsites.net>, May 2014) .

Solutions can neither be expected from the EPO (see chapter 6) nor from the breeding sector itself. For example, the PINTO database was developed by the European Seeds Association (ESA) to provide more transparency on patents in plant breeding. However, although the ESA raised many expectations it is not supported by the whole breeding sector and as mentioned, several of the big companies have failed to cooperate. As a result, there is no transparency for breeders or farmers about potential infringements of patents if they use varieties being sold on the market. This leads to substantial costs for legal consultancy, a high level of uncertainty and is frustrating especially for smaller breeders. The whole situation has, in fact, created a systemic obstacle to innovation and uncertainty is being hugely increased by extremely broad patent claims, as explained in the report from Wageningen (Louwaars et al., 2009). This uncertainty is being used to systematically hinder breeding. A previous report highlights the case of a breeder working with sunflowers (Then & Tippe, 2012) who, upon request, received sunflower seeds from Syngenta and from Pioneer, which he needed to develop his own new varieties. Contrary to plant variety protection, where unrestricted use of genetic material is provided to enable further breeding, he found that the use of the seed material was greatly restricted, as explained by the proprietary claims attached to the seed packages. For example, Pioneer set the following preconditions for any usage of the seeds:

- “By opening this bag [...] you agree with the terms set hereafter:
The material contained in this [...] seed sample is proprietary and owned by or licensed to Pioneer Overseas Corporation (“Pioneer”) [...]*
- The Recipient expressly undertakes: [...]*
- *Not to sell, transfer or use the seeds, plants, pollen of plants or grain for breeding, research and unauthorised reproduction [...]*
 - *Not to use, nor allow any third party to use the seeds, plants, parts of plants, pollen or seed produced from these seeds for the purpose of plant breeding. [...]”*

Since the breeder had no certainty at all about whether these claims were based on a patent (Pioneer has applied for patents on sunflowers) and could be enforced, or whether the seeds were protected under PVP law that allows further breeding, he was caught up in major legal uncertainties that impede further breeding to obtain better seeds.

Syngenta tried to impose very similar legal restrictions:

“[...] Important notice: The use of this product is restricted. [...] By opening and using this bag of seed, you confirm your commitment to comply with these use restrictions. This product [...] is proprietary to Syngenta Crop Protection AG or its licensors and is protected by intellectual property rights. [...] Unless expressly permitted by law, use of the seed for producing seed for re-planting, research, breeding, molecular or genetic characterization or genetic makeup is strictly prohibited.”

Syngenta does not hold patents on sunflowers, but it might be the case that Syngenta holds licenses on the patents of other institutions. Interestingly, soon after the report of No Patents on Seeds was published, Syngenta created a new database and informed other breeders about their patents on vegetables²⁰,

²⁰ <http://www.sg-vegetables.com/licensing/about/3-overview-of-technologies>

ostensibly to provide more transparency. However, this information does not help the breeder working on sunflowers. Sunflowers are not considered to be a “vegetable” and the Syngenta database only provides information about the company’s own patents but not about other patents being used under license, so it in no way resolves the uncertainty in the specific case.

By not saying which kind of IPR is protecting the seeds, companies like Syngenta or Pioneer can, and are, intimidating breeders to stop them using the seeds for further breeding. If the IPR in question is a plant variety protection - breeders would be free to use it for further breeding because this is expressly permitted by law. If the IPR in question is a patent for use in further breeding it would probably not be allowed, at least in some countries. It is problematic and deceptive not to tell the user which kind of IPR the seeds are protected by.

6. Legal analysis: Why EPO decision-making will not solve the problem

The history of patent law gives the impression that industry and the EPO have more or less joined together in their efforts to use legal loopholes to grant patents on plants and animals. As a consequence, the legal prohibitions of Article 53 (b) have been mostly eroded and can hardly be applied in a meaningful way. In short, in current EPO practice, the following are considered patentable:

- products derived from crossing and selection (seed, fruits, plants, breeding material);
- all steps in the breeding process except the combination of crossing and subsequent selection (such as selection before crossing);
- plants and animals described or selected for their genetic condition or phenotype (characteristics such as growth, components, resistances);
- all plants and animals with a change in their genetic condition that is not caused by the combination of the whole genome (such as random mutagenesis);
- plant varieties as long as no defined varieties are claimed explicitly.

It appears that the EPO have, indeed, intentionally created an unprecedented situation full of legal absurdities. The patents with the broadest claims are the ones most likely to be granted by the EPO as long as specific varieties or specific processes for essentially biological breeding are not claimed explicitly. However, in essence, these patents cover plant varieties as well as products and processes of essentially biological processes for breeding and have, in fact, already been granted in some cases.

Recently, the EPO decided to refer other cases to its Enlarged Board of Appeal. The new G2/12 and G2/13 referrals to the Enlarged Board of Appeal on the patentability of plants are directly related to the earlier referrals of the patents on broccoli (EP 1069819, G2/13) and on tomatoes (EP 1211926, G2/12). The reason for the new referrals is that the Technical Board of Appeal (T1246/06) has raised concerns that if patents on products such as seeds and plants derived from essentially biological breeding are allowed, this

“would make the circumvention of the exclusion in many cases a matter of skillful claim drafting”

The Technical Board of Appeal is warning that the prohibition of patents on processes in conventional breeding can only be implemented, if the products derived from these processes are excluded from patenting as well. If they are not excluded then breeders cannot make use of those particular breeding processes, since this would inevitably lead to patented products. Thus according to the Technical Board of Appeal, this could create a situation where

“plant breeders would be more severely restricted in performing essentially biological processes”.

It is hard to say why the Technical Board of Appeal made these observations. It might just be a strategy designed to give the impression to the public that the EPO is dealing with some of the concerns. It could also be that the chair of the Technical Board (no longer working for the EPO) had a real interest in tackling these issues. Whatever the reason for the new referrals, there is also a more general problem with the pending cases that is likely to have a severe impact on the outcome. Both the G2/12 and G2/13 cases are a direct result of the G2/07 and G1/08 decisions. However, these previous decisions lack a sufficiently

clear and comprehensive explanation of what is considered to be essentially biological or conventional or traditional breeding and what is 'non-essentially biological' (see below).

Regardless, the decisive question, of how patents on plant breeding can be excluded in a way that access to genetic resources is not hampered is still not on the EPO agenda, and not being asked in any of the cases pending. Whatever the Enlarged Board of Appeal decides, it is very unlikely to stop patents on conventional plant and animal breeding. Political decision-making is the only way to resolve this situation (see chapter 7).

6.1 What is “essentially biological” breeding?

The main issue in the G2/12 and G 2/13 referrals is whether products derived from essentially biological processes of breeding can be patented. The Enlarged Board of Appeal has to answer the following question:

“Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit?”

There is no doubt that this is an important question. But as shown above, it touches on just one of several problematic issues. Even if the EPO decided that the answer to this question is “Yes”, (and products derived from essentially biological processes are declared as being not patentable) this might not change a lot about patents being granted, because what is considered as essentially biological by the EPO (sexually crossing and subsequent selecting) is only just one part of what is relevant for conventional breeding in plant and animals. It will still be possible to grant patents on products derived from mutation breeding, on processes for selection before crossing (such as phenotype or genotype) or on breeding material and others. Some examples are the selection of native variants of soybeans before crossing (EP2134870) or patents based on a phenotypical description of plants (EP1973396) which might still be patentable, or patents on animal sperm cells (EP 1263521) and other breeding material needed for conventional breeding.

To solve the problem the EPO has to provide a proper definition of “essentially biological” breeding that covers all the relevant steps and processes and material used in or produced by conventional breeding. In this context, conventional breeding should be defined in contrast to genetic engineering that is within the scope of regulation under Directive 2001/18 (see below). The interpretation of patent law should also take into account “real life” practices and implications for conventional breeding. This was not settled in the G2/07 and G1/08 decisions and G2/12 and G2/13 are likely to suffer from same deficiencies.

6.2 What is not “essentially biological?”

The G2 /07 and G1/08 decisions have created further uncertainties in regard to what exactly should be considered as patentable. In particular, there is no clear line between genetic engineering (regarded as patentable by EPO) and conventional “essentially biological” breeding (not patentable). Instead of referring to established definitions such as those in EU Directive 2001/18, the G2/07 and G1/08 decisions vaguely state:

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.

This wording of the decision (“trait is not the result of the mixing of the genes of the plants chosen for sexual crossing”) can be interpreted in many ways. As mentioned, for example, random mutagenesis might fulfill the requirements of patentability according to this decision.

Clarification would have been greater if the regulatory approach of EU Directive 2001/18 had been used. This Directive defines GMOs (genetically modified organisms) that need to be regulated as organisms produced from processes using isolated DNA or of cell fusion which does not occur under conventional breeding conditions (Annex 1 A, Part 1). Other methods of genetic modification that do not fall under this definition are excluded. For example mutation breeding is named in Article 3 and Annex 1B as something that does not fall under the regulatory scope of the Directive.

As mentioned, there are good reasons from the perspective of organic breeders to question whether a breeding method can be considered ‘traditional’ if it is triggered by chemical compounds or radiation. However, in the context of patent law, and also in light of the EU Directive 2001/18, the level of technical interaction with the plant material is a much more useful criterion than simply using the terms like ‘traditional’. In mutagenesis the technicality of the process is low, as mutagenesis means interacting in non-targeted way with the whole cells and the whole genomes²¹. The difference becomes evident by comparison with genetic engineering: This technology is performed by inserting previously isolated DNA, by invading the cells with technical means and acting directly at the DNA level. Thus methods such as random mutagenesis fall within the prohibition of Art 53 (b) EPC, and are non-patentable because they are essentially biological, even though it might not be considered to be ‘traditional’.

Also decision G 1/98 refers to organisms that are produced by using isolated genetic material (that might be patentable) and therefore this decision seems to share similar reasoning and terminology with EU Directive 2001/18. But this reasoning was not followed by G2/07 and G1/08. As a result, there is too much room for uncertainties about the processes considered to be not essentially biological, and G2/12 and G2/13 are likely to suffer from same deficiencies.

21 Within certain limitations, it can even be considered as ‘natural’ since it can be understood as acceleration of processes that also occur in nature and evolution.

6.3 How about cleverly worded claims?

The wording in several patents (see chapter 4) appears to be cleverly formulated in order to circumvent the prohibitions. For example, some of the plants claimed are very generally described as products of an ,introgression‘ of a particular genetic trait. This terminology can include any method such as crossing and selection, cell fusion or genetic engineering. The wording of such claims includes, but is not confined to, the crossing of whole genomes. It is a general principle in patent law that patents on products are not confined to methods used for their production, but are entitled to ,absolute protection‘, covering all products no matter how they are produced. So if such patents are granted, their scope covers all plants with the genetic characteristics as claimed – no matter how the genetic conditions are introduced. Monsanto, for example, uses such wording in a patent on melons (EP 1962578). In this patent, a virus resistant melon plant is claimed, “comprising an introgression” from another melon plant. As such the wording of a claim is not confined to any method, and the scope of the patent is not restricted to particular methods. This patent simply covers all melon plants with the genetic condition as described, also those derived from crossing and selecting. It is very unlikely that this problem will be solved by the pending decisions G2/12 and G2/13.

6.4 What about plant varieties?

As explained, current EPO practice renders the exclusion of plant and animal varieties more or less meaningless. This practice is being reaffirmed in the pending cases. In the case of the tomato (pending as G2/12), the Technical Board of Appeal (T1246/06) discussed whether the patent would also violate the prohibition of patents on plant varieties. However these concerns were rejected. The Technical Board of Appeal stated:

“a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties”

As a result, the Technical Board of appeal at the EPO appears to be confirming that plant varieties can actually be covered by patents despite the fact that patents on plant and animal varieties are excluded explicitly by the wording of Art 53(b) EPC (see also chapter 3).

This reasoning does not take the main problem into account. If patents are granted that cover plant varieties, the legislator’s intention to exclude plant varieties is completely cancelled out. Thus, the so-called breeders’ exemption established as a basic element of PVP law, which aims to allow continuous breeding and innovation, would be undermined and have the opposite of the intended effect. There is no justified expectation that the EPO will solve this problem under the pending cases.

6.5 The preliminary opinion of the Enlarged Board of Appeal

In July 2014, the Enlarged Board of Appeal published a preliminary opinion on G2/12 and G2/13, giving some first observations and providing some relevant questions in preparation for the public hearing on 27 October 2014.

The Board explicitly states that the upcoming decision will not tackle the issue of plant varieties. Further, it points out that there is no indication in the text of the law that products derived from essentially biological breeding are non-patentable. There is no mention that the definition of essentially biological processes needs further discussion. So it appears that the Enlarged Board of Appeal will follow the approach it took in making the previous decisions.

At the same time, the Board states that the forwarded questions do not relate to problems with the issue but to the interpretation of law:

“It should be noted that the issues before the Enlarged Board relate to questions of law rather than the economic or rather general aspects mentioned in some of the amici curiae letters.”

But as shown, the text of the law is open to interpretation and leaves the decisive question of whose interests will guide the Board in its decision-making unanswered. Will it act in the interests of the patent industry or those of general society? Trying to restrict the issue to a matter of law is simply a strategy to hide behind a legal text that has more than enough grey areas to satisfy the needs of industry. For decades decision-making at the EPO has mostly been concerned with duplicitous interpretations of patent law and skillful wording of the claims. It has solved none of the real pending problems in the context of plant and animal patents.

Looking at this communication from the Enlarged Board of Appeal, it seems difficult to predict how the Board will decide the question of whether products derived from essentially biological processes can be defined as patentable inventions. But in any case it seems highly unlikely that the Board is willing to answer the real questions here.

7. The way forward: the task for the regulators

The prohibition of patents on plant and animal varieties as well on products and processes for conventional breeding must not be seen as a legal concept based on purely technical criteria such as inventiveness. Rather it has to be put in the context of the needs and interests of consumers, farmers and traditional breeders.

As described, patents on plants and animals can interrupt the process of innovation in breeding, block access to essential plant and animal genetic resources, obstruct farming activity and restrict freedom of choice. Unquestionably, these patents promote market concentration, hamper competition, and serve to promote unjust monopoly rights.

The scope of the patents that are granted is often extremely broad and covers the whole chain of food production. They are, in fact, designed to take control of resources needed for our daily lives. If the current trend is not halted and reversed it is not unlikely that in the near future just a few companies will be able to decide which plants are bred, grown and harvested.

Seen from this perspective, maintaining and safeguarding free access to material needed for plant and animal breeding has to be a political priority. Any measures taken must primarily comply with the needs of farmers, traditional breeders and consumers, and not with the interests of the 'patent industry'.

7.1 The European Parliament Resolution

Patents on the conventional breeding of plants and animals can only be stopped if at least all processes, materials and products used in (or developed by) conventional breeding are defined as being non-patentable (or essentially biological).

Such an interpretation of patent law could be applied without changing the current law as there is no real contradiction. This was made explicit in a European Parliament resolution in 2012²², which gave a substantially different interpretation of EU Directive 98/44 and its meaning regarding essentially biological processes than is currently applied by the EPO. According to the text of the resolution, the EU Parliament

"3. Welcomes the decisions of the Enlarged Board of Appeal of the EPO in the so-called 'broccoli' (G 2/07) and 'tomato' (G 1/08) cases, dealing with the correct interpretation of the term 'essentially biological processes for the production of plants (or animals)' used in Directive 98/44/EC and the European Patent Convention to exclude such processes from patentability;

4. Calls on the EPO also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding;(...)

6. Welcomes the recent decision of the European Patent Office in the WARF case and of the European Court of Justice in the Brüstle case, as they appropriately interpret Directive 98/44/EC and give important indications on the so-called whole content approach; calls on the European Commission to draw the appropriate consequences from these decisions also in other relevant policy areas in order to bring EU policy in line with these decision. (...)"

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

As careful reading of the EU Parliament's resolution shows, it is assumed that in plant breeding all conventional breeding methods (such as selection before crossing, usage of mutations, propagation without crossing) as well as all products and breeding material derived thereof, have to be excluded from patentability. The new breeding technologies, known as SMART breeding (precision breeding) are excluded. Furthermore, it is stated that it is not only the (skillful) wording of the claims, but the content of the whole patent ("whole content approach") that has to be taken into account during the examination of a patent. As a result, it would no longer be possible to circumvent the current exceptions of patentability simply by cleverly wording the claims. In the same way, the context of the invention has to be considered such as pre-treatment steps, consequences and usages of the patent.

This resolution is very relevant for decision-making at the EPO: the EU Parliament adopted EU Directive 98/44 and then it became a part of the Implementation Regulation of the EPC. Therefore, this interpretation of current EU patent law should also be applied in EPO practice. Political action is required in the event that the EPO does not adopt this interpretation of the EU Parliament resolution into its implementation regulation.

7.2 Actions that need to be taken by the contracting states of the EPO

To some extent the interpretation adopted by the European Parliament is already integrated in German and Dutch patent law. According to these national laws, patents on products derived from conventional breeding are already excluded by explicit wording in their national patent laws. In addition, the coalition treaty of the German government announced a European initiative to prohibit patents on essentially biological breeding. At the same time these national laws suffer from not having an adequate definition of how such a prohibition can be implemented in a way that conventional plant breeding can no longer be impeded by patents.

The decision on the patentability of our food plants and farm animals cannot be left to the EPO, which is driven by its own vested interests.

There are three ways in which contracting states of the EPO can take action :

- introducing a full breeders' and farmers' exemption into patent law
- making a legal change to the EU Patent directive 98/44
- changing the EPC implementation regulation.

These three possibilities have some strengths and weaknesses:

- A full breeders and farmers exemption could – for example - be included in the unitary patent system. As a result, access to genetic resources would no longer be blocked. However, this approach might also require a change in EU Patent Directive 98/44, which does not foresee such an exemption. There has already been a controversial debate about introducing a breeders' exemption under the Unitary Patent law to provide access to patented material as it is foreseen under PVP law. So far, the Unitary Patent only provides a restricted breeders' exemption that does not allow commercial use of new plants derived from material from patented plants. Breeders are unlikely to invest into the breeding of new varieties if marketing them can be controlled by a patent holder.

This situation is damaging incentive and is likely to create a fundamental frustration at least for smaller and middle-sized breeders. In addition to the introduction of a full breeder' exemption, there must be legal certainty that farmers will not face litigation for infringement of patent rights whilst, at the same time, there must be a strengthening of 'farmers rights' under PVP law.

- A change in the EU Patent Directive 98/44 EC could create robust legal certainty. A prohibition of patents on plants and animals and genetic resources would solve most of the problems in this context, and any change in the EU Patent Directive would be mirrored in the interpretation of the EPC and EPO practice. However, the EU Commission does not seem willing to reopen the text of the Directive at the present time. Substantial progress on this matter would require much more pressure from EU member states.
- A change in the Implementation Regulation of the EPC would not require a change in law and could be achieved by a majority vote in the Administrative Council of the EPO. Most of the points raised by the European Parliament could be resolved by a change in EPC interpretation that could be rectified in the wording of the implementation regulation (see overview below). However, some legal ambiguity would remain for some of the provisions of the EU Patent Directive 98/44, which still would not exclude patents on plants and animals. Nevertheless, a change in the implementation regulation would be an important first step.

Proposed changes of the Implementation Regulation of the European Patent Convention (EPC) and national patent legislation to meet the requirements of the European Parliament resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP))¹ and to clarify that farm animals are excluded from patentability

Existing implementation regulation of the EPC ²	Proposed additions	Comments
Rule 26 General and definitions (1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.	In assessing inventions and patent applications under the exclusion provisions of Art. 53 EPC the whole content of the specification of the patent application shall be considered independently from the claims drafted for examination purposes. Exclusion of inventions from patenting under Art. 53 EPC shall not be circumvented by purposive drafting of the claims of patent applications. Technically un-avoidable pre-process steps and technically un-avoidable post-process steps and/or un-avoidable post-process uses of the products shall constitute part of the invention, even if they are not explicitly disclosed in the specification and/or the claims of a patent application.	In the past existing exclusions (plant varieties, biological processes) have often been circumvented by creative drafting of the claims – although the invention as described in the patent application was falling under exclusion. This way to circumvent exclusions should be stopped by this amendment. This is in line with the Resolution of the European Parliament, demand Nr. 6
(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.	Products derived from conventional breeding, all methods used in conventional breeding, including such as SMART breeding (precision breeding) and breeding material used for conventional breeding shall be excluded from patenting under Art. 53 (b) EPC.	This is in line with the resolution of the European Parliament, demand Nr. 4
Rule 28 Exceptions to patentability Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.	This exclusion shall be applied generally to animals for agricultural purposes, in particular to animals used for food production.	While genetic engineering in animals can be considered in general as being likely to cause suffering, animals for food production do not serve medical benefits and therefore are considered as being not patentable. This is in line with the text and reasoning behind EU Patent Directive 98/44.

¹ www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN

² See [http://documents.epo.org/projects/babylon/eponet.nsf/0/7bcb229e032863dc12577ec004ada98/\\$FILE/EPC_14th_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7bcb229e032863dc12577ec004ada98/$FILE/EPC_14th_edition.pdf), corresponding with national law in the EU and the EU Patent Directive 98/44, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>

Table 4: Proposal for some changes in the implementation regulation

8. Conclusion and demands

The decision on whether patents on seeds, plants, animals are allowable cannot be decided by the EPO, which is driven by its own vested interests. It was the EPO that systematically eroded the current prohibitions in Article 53 (b) EPC of patent law in the interest of companies receiving revenues from patented products and institutions profiting from the granting of patents.

The EPO and the interests of industry were the driving factors in previous years that contributed to turning the patent system into an instrument allowing the misappropriation of biological resources needed to produce food and energy away from one which promotes innovation in the interests of society at large. There is a clear need to completely reorganise the EPO so that it can meet the needs of society in future. At the same time there is an urgent need to make political decisions on patents on seeds and animals in the immediate future.

We are already at a critical point in the overall development. The market concentration in seeds markets is extremely high in several sectors, especially in seeds for vegetables, maize and soybeans. Several thousand patents on plants and seeds have been applied for or granted, with an increasing number of patents on conventional breeding.

These developments are not only a problem for specific sectors or regions, but can endanger agrobiodiversity, ecosystems and our adaptability in food production systems to challenges such as climate change. Therefore, it constitutes a huge risk to global food security as well as to regional food sovereignty.

Maintaining and safeguarding free access to material needed for plant and animal breeding and agricultural production has to become a political priority. Any measures taken have to primarily comply with the needs of farmers, traditional breeders and consumers, and not with the interests of the 'patent industry'.

Political decisions need to be made to stop patents on resources needed for our daily lives. This means taking two major steps:

- in the short term, changing the text of the Implementation Regulation of the EPO to bring it in line with the interpretation of EU patent directive 98/44 as provided by the European Parliament
- a change in European patent laws to exclude patents on genetic resources, on plants and animals.

Further, we need to make sure that current negotiations on the free trade agreements such as CETA and TTIP do not counteract the possibilities for Europe and the EU to prohibit patents in future that are currently considered as being patentable by the EPO.

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