Patents on plants and animals – time to act for European politicians

Report published by No Patents on Seeds!, 2016
Christoph Then and Ruth Tippe

no patents on seeds

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The report was drawn up after discussions within the coalition of No Patents on Seeds.
Some of the positions presented in this report are not shared by all the members of the coalition, which are however all sharing the necessity to ban immediately every patent on plants, animals, theirs parts or their genetic components.

The organisations behind *No Patents on Seeds!* are Arche Noah (Austria), Bionext (Netherlands), The Berne Declaration (Switzerland), GeneWatch (UK), Greenpeace, Misereor (Germany), Development Fund (Norway), NOAH (Denmark), No Patents on Life (Germany), ProSpecieRara, Red de Semillas (Spain), Rete Semi Rurali (Italy), Reseau Semences Paysannes (France) and Swissaid (Switzerland).

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Imprint

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Content

Summary

On 25 March 2015 the Enlarged Board of Appeal of the European Patent Office (EPO) confirmed an unacceptable interpretation of the current patent law: While processes for conventional breeding cannot be patented, plants and animals stemming from these processes are patentable. This is not only contradictory in itself, but it also undermines the prohibitions in European patent law: "Plant and animal varieties or essentially biological processes for production plants and animals" are excluded from patentability (Art 53 b, EPC). Because the Enlarged Board of Appeal would be binding for all other EPO decisions in this context, now the rules for the interpretation of the European Patent Convention have to be changed, to strengthen the current prohibitions in European Patent Law. This could be achieved by the Administrative Council of the European Patent Organisation by changing the Implementing Regulation. The existing prohibitions can also be strengthened by the institutions of the EU which can take decisions on the interpretation of the EU Patent Directive 98/44. In parallel, national patent laws can be changed accordingly.

A situation of intentional legal absurdity

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 2800 patents on plants and 1500 patents on animals have been granted in Europe since the 1980s. Around 7000 patent applications for plants and around 5000 patents for animals are pending. The EPO has already granted around 180 patents that concern on conventional breeding and about 1400 such patent applications are filed. 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 this report, several cases of granted patents on conventional bred plants are presented. These included patents on peppers bred from wild varieties originating from Jamaica, tomatoes that were developed using the international gene bank in Germany, melons using resources from India 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.

The EPO has in fact intentionally created a situation full of legal absurdities. Patents on essentially biological processes for breeding are excluded but the plants and animals derived thereof are patentable. This is the exact opposite of what the legislators intended: The patents provide a monopoly on all plants with the respective characteristics, the seeds and even the fruits and food derived thereof. The patents also cover plant varieties: If all plants with specific characteristics are claimed, there is a high likelihood that the patent will be granted. The applicant only has to make sure that no varieties are claimed explicitly. In essence, the patents as granted by the EPO cover plant varieties as well as products derived from conventional breeding.

Patents cover whole chain of food production

There are already several examples that show how plants and animals are turned into a so-called invention of industry: Trivial technical steps such as analyzing natural genetic conditions, measuring compounds (like oil or protein), crossing-in native traits which already exist in landraces or wild relatives or just by describing general characteristics can render plants and animals a so-called inventions monopolised by patents. Many of the patents and patent applications are based on biopiracy, privatizing biodiversity stemming from the countries of the south. In most cases, these patents cover the whole value chain from breeding to harvest of food and feed production. Patents cover all kind of food crops: Vegetables such as tomatoes, broccoli, pepper, lettuce as well as soybeans, maize and wheat. Patents also cover edible parts of the plants such as the fruits or food processed such as beer and bread. These patents are nothing else than an abuse of patent law, which should not be applicable for discoveries or natural resources but only for real inventions. This abuse allows a few companies to take over control over basic resources needed for our daily life.

Concentration process in seed business

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.

There are particular groups that gain massive profits from these patents: Companies such as Monsanto, Dupont, Syngenta which are filing more and more patents on seeds. Furthermore, institutions and individuals which base their business on legal activities around patents such as patent lawyers, consulting companies and last not least the European Patent Office also profit significantly: The EPO is financed by granting patents and more or less plays the role of delivering service to industry. These particular stakeholders are the main drivers for the creation a patent law which does not serve the society, but only some interest groups.

On the other hand, breeders, farmers, growers, food producers and consumers are those that are severely impacted by the negative consequences of this development: Patents on plants and animals will foster further market concentration, making farmers and other actors of the food supply chain more and more dependent on just a few big multinational companies. Increasing concentration and monopolisation of the breeding sector disables competition, hampers innovation and gives the power to decide what is grown in the fields and which price we have to pay for it, to a few international corporates.

Danger to the food system

This development is not just a problem for specific markets or regions; it will ultimately endanger the agro-biodiversity, the 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.

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'.

Political action needed

European politicians have to act now! As a first step, Member States of the European Patent Office (EPO) should take initiative at the Administrative Council, which is the assembly representing the Member States of the EPO. It can change the current rules of patent law by amending the Implementing Regulation to the European Patent Convention. The existing prohibitions can also be strengthened by the institutions of the EU which can take decisions on the interpretation of the EU Patent Directive 98/44. National laws such as in Germany and the Netherlands show that patents on plants and animals derived from conventional breeding can be prohibited on national level. Further the European Parliament adopted a resolution on 10 May 2012 on the patenting of essential biological processes, in which "the European Parliament 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." [1]European governments should follow this line and prohibit patents on plants and animals derived from conventional breeding, including breeding material and genetic resources in a first step.

On the midterm, the European Patent law should be changed to exclude all breeding processes and breeding material, plants, animals, genetic resources, native traits and food derived thereof from patentability.

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

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 2800 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 that concern conventional breeding. Around 1400 such applications have been filed and around 180 patents have been granted.

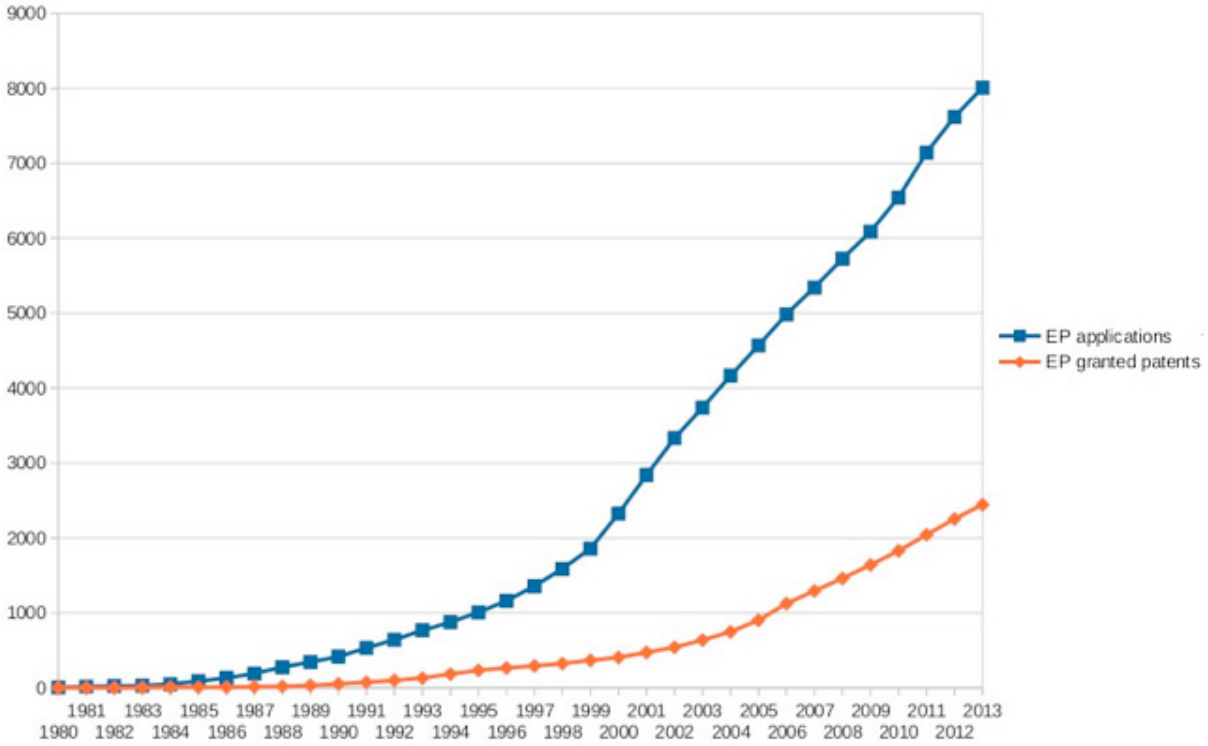

Figure 1: Number of patent applications and patents granted on plants at the European Patent Office in Munich (accumulated) Research according to official classifications (IPC = A01H or C12N001582).

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 several

sources[2], 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 ETC-Group, 2011; EU Commission, 2013a.

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 1973[3].

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, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey.

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

3 http://www.epo.org/about-us/organisation/foundation.html

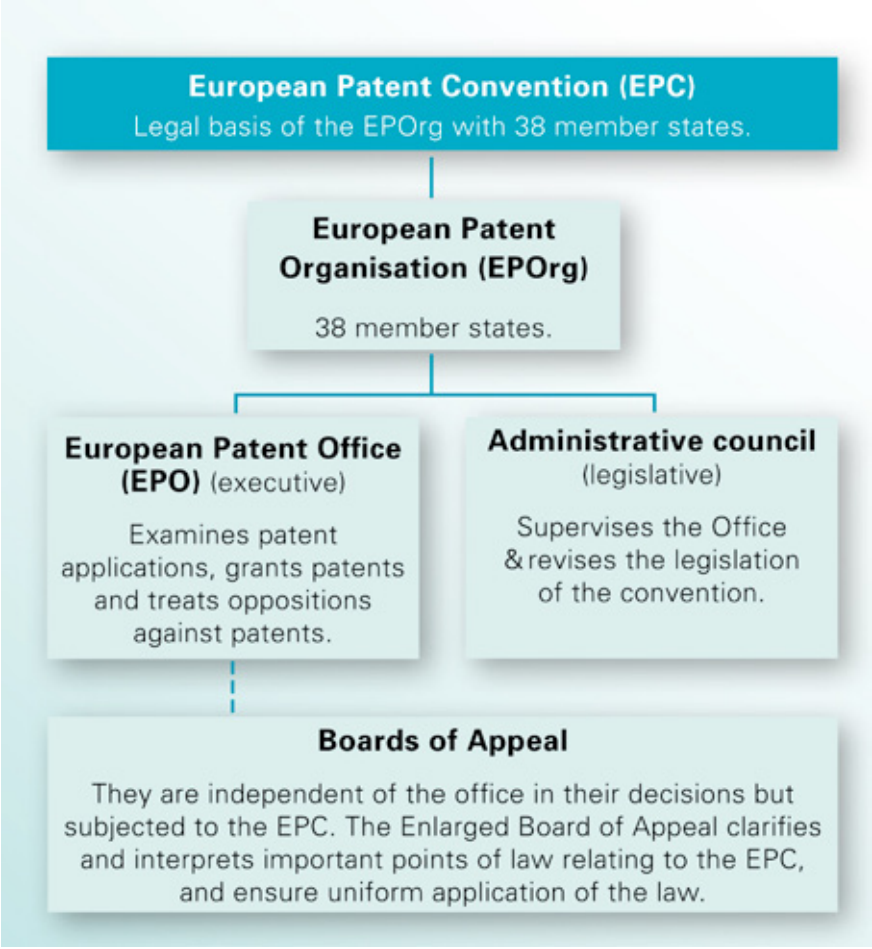

Figure 3: Structure of European Patent Organisation, EPOrg (source: Lebrecht & Meienberg, 2014)

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 €)[4] is mostly based on fees from patent holders (revenue from patent and procedural fees in 2013: 1,5 Billion €[5]). Consequently, the patent office has its own vested interest in receiving applications and

4 http://documents.epo.org/projects/babylon/eponet.nsf/0/125011cc1d9b8995c1257c92004b0728/$FILE/epo_facts_and_figures_2014_en.pdf

5 http://documents.epo.org/projects/babylon/eponet.nsf/0/094DF1067B07003EC1257D040040A402/$File/financial_statements_2013_en.pdf

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.

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 BUSINESSEUROPE and the Institute of Professional Representatives at the European Patent Office (epi).

  BUSINESSEUROPE is an umbrella organisation for national business federations and industry in 35 countries[6].

  The Institute of Professional Representatives at the European Patent Office (epi) represents the European patent attorneys[7]. There are nearly 4000 registered European Patent Attorneys in Germany, and more than 2000 in UK[8]. 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.

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6 http://www.businesseurope.eu/content/default.asp?PageID=600

7 http://www.patentepi.com/en/the-institute/list-of-professional-representatives/

8 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)[9] 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 2,2 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"[10] that is meant to ensure supranational protection in the Member States of the EU. For the first time there will be a European patent court, the so-called "Unified Patent Court"[11].

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.

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9 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044
10 http://www.epo.org/news-issues/issues/unitary-patent.html
11 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)[12] 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)[13] 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)[14].

In 2013, the negotiations started on the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US[15]. 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.

12 http://www.wipo.int/portal/en/index.html
13 http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
14 http://www.wto.org/english/docs_e/legal_e/27-trips.pdf
15 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 1999 a far reaching decision was made in order to overcome the existing legal barriers and to serve the interests of industry: The Enlarged Board of Appeal of the EPO made the decision (G1/98) that patents not directed to specific plant or animal varieties, but to more general claim plants and animals with interesting breeding characteristics, could be granted.

By doing so, the Enlarged Board of Appeal referred to the EU patent directive ("Legal Protection of Biotechnological Inventions", 98/44 EC). 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.

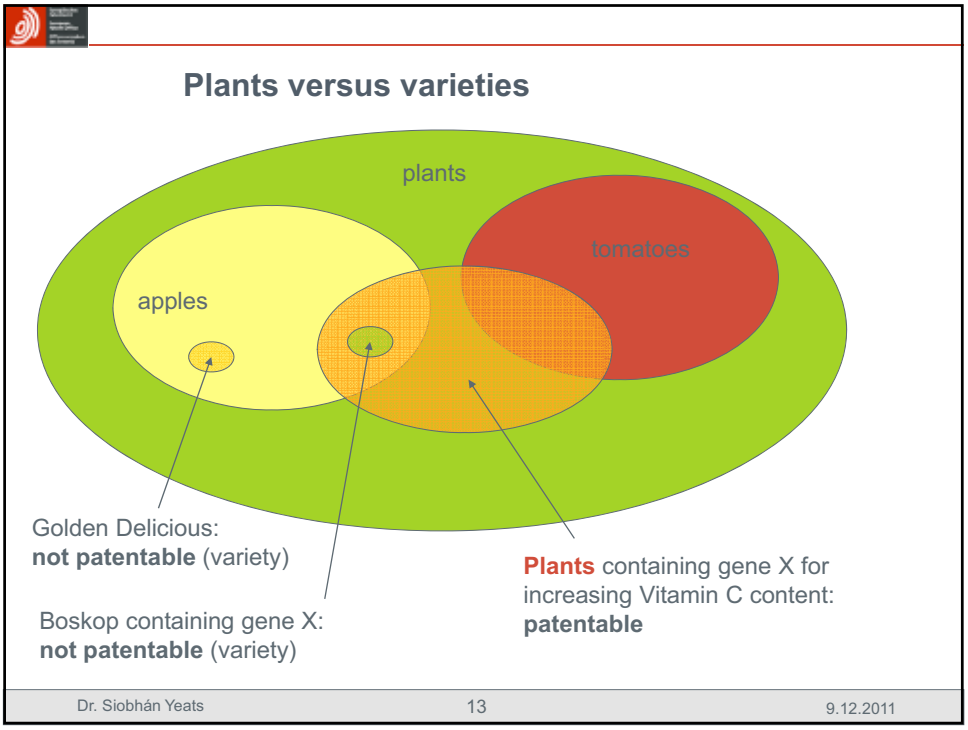

Figure 4: This slide shows how the European Patent Office currently interprets the prohibition of patents on plant varieties. While is not possible to patent a defined variety of apples with a higher content in Vitamin C, it is possible to grant a general claim on plants with an elevated content of vitamins 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?

In 2015, the Enlarged Board of the EPO finally gave an extremely biased interpretation of current patent law: While processes for conventional breeding cannot be patented, plants and animals stemming from these processes are patentable (decisions G02/12 and G02/13). This is not only contradictory in itself, but it also undermines the prohibitions in European patent law. This is also noticed by the EPO. As the Technical Board of Appeal in its interlocutory decision of 31 May 2012 wrote (case T1242/06[16]):

The board still has to address the further argument that, (…) it would be wrong to allow the to allow the claimed subject-matter to be patented, since this would render the exclusion of essentially biological processes for the production of plants completely ineffective, thereby frustrating the legislative purpose behind the process exclusion in Article 53(b) EPC. (Nr 40)

Disregarding the process exclusion in the examination of product claims altogether would have the general consequence that for many plant breeding inventions patent applicants and proprietors could easily overcome the process exclusion of Article 53(b) EPC by relying on product claims providing a broad protection which encompasses that which would have been provided by an excluded process claim (...). (Nr. 47)

Following this reasoning of the European Patent Office itself, it does not make any sense to exclude just the processes for breeding while allowing patents on plants and animals: It would be too easy to escape the prohibition just by clever drafting of the claims. In result, the prohibition of Article 53b can no longer be applied in a meaningful way.

Thus 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 (T1242/06), this could create a situation where

"plant breeders would be more severely restricted in performing essentially biological processes". (Nr. 64)

16 http://www.epo.org/law-practice/case-law-appeals/pdf/t061242ex2.pdf

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: Plants and animals derived from conventional breeding can be patented if the processes for breeding are not claimed. The patents as granted by the EPO also cover plant varieties: If the patent claims are directed to breeding characteristics of a plant by, for example, describing its genome, its compounds or agronomic features the patent has good changes to get granted. 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 are not claimed explicitly. In essence, the patents as granted by the EPO are covering 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?	Products derived from processes based on sexual crossing of whole genomes and further selection can be patented.

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

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 application of the EPC by the EPO, 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 specific characteristics (such as growth, components, resistances, marker genes);
- all plants and animals with a change in their genetic condition that is not caused by the recombination 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.

4. Patents granted on plants and animals

Around 2800 patents on plants and 1600 patents on animals have been granted in Europe since the 1980s. Around 7000 patent applications on plants and around 5000 patents on animals are pending. The EPO has already granted more than 180 patents on conventional breeding and around 1400 applications in this field are filed already.

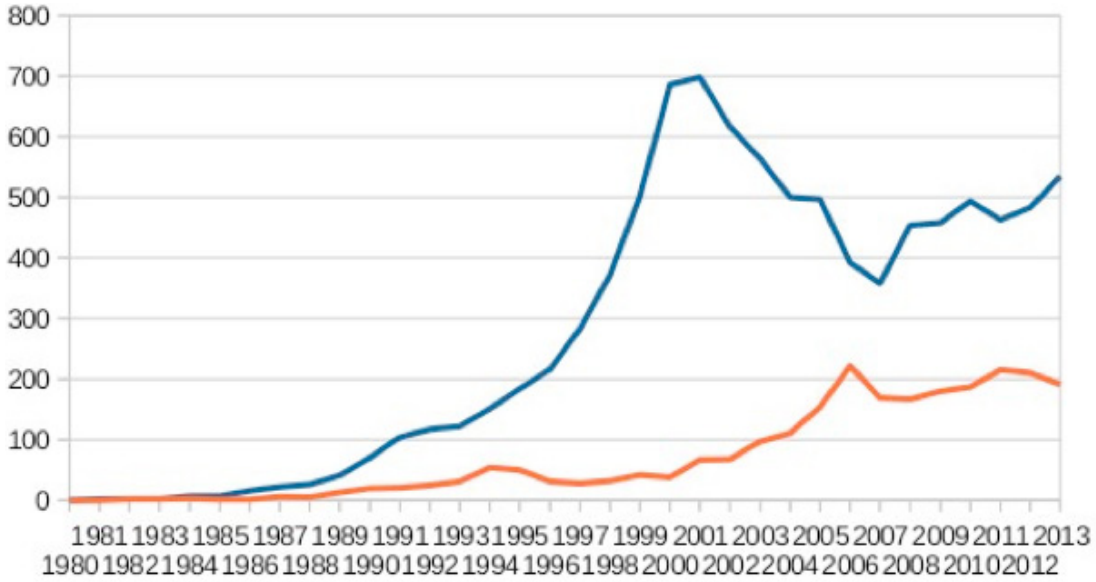

Figure 5: Patents on plants - number of patent applications on all plants under PCT/WIPO (WO) as well as of patents on plants granted by the EPO (lower line) per year. Research according to official classifications (IPC A01H or C12N001582).

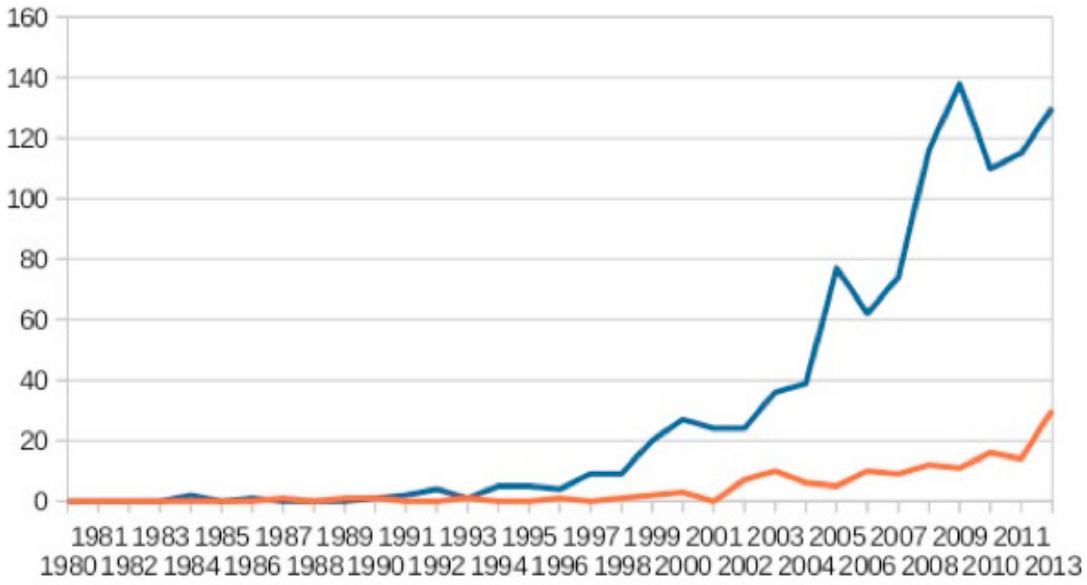

Figure 6: Number of patent applications (EP) and patents granted concerning conventional plant breeding (EP B – lower line) by the EPO per year (own research).

4.1 Case studies: recently granted patents on plants

The precedent case: Patent on broccoli

In the year 2002 the EPO granted a patent on broccoli (EP 1069819) with a high content of glucosinolates which are supposed to render positive health effects. The plants are stemming from crossings with wild variants of broccoli with commercial varieties. The patent covers the plants, the seeds and the harvested food. The patent claims read:

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

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

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

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

11. Seed of a broccoli plant (...)

The patent is used by Monsanto which is marketing the broccoli under the brand "beneforte" as "super broccoli" in countries such as the US an UK. The patent, together with a patent on tomatoes with a reduced content of water (EP 1211926) became the precedent case at the EPO for patents on plants derived from conventional breeding. 2010 the EPO decided that he process for breeding the broccoli and the tomato can not be patented, because they have to be considered as "essential biological" (decision G1/07, G2/08). In 2015 however, the EPO decided that the plants, the seeds and the harvested vegetables are regarded as patentable inventions (decision G2/12 and G2/13).

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 (G2/07 and G1/08) – 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. revoked

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 and should therefore not be patentable at all. Random Mutagenesis only involves a low level of technicality as long as itinteracts in a non-targeted way with the whole cells and the whole genomes.es.

Syngenta´s healthy tomatoes

A monopoly on specific tomatoes with a higher content of healthy compounds known as flavonols was granted by the EPO to the Swiss company Syngenta in August 2015. The patent covers the plants, the seeds and the fruits. Patent EP1515600 describes the crossing of wild tomatoes with domesticated varieties. The plants are not genetically engineered but derived from classical breeding. The original tomatoes were collected in countries such as Peru.

Monsanto´s Indian Melon

In May 2011, the US company Monsanto was awarded a European patent on conventionally bred melons (EP 1 962 578). These melons which originally stem from India have a natural resistance to certain plant viruses. Using conventional breeding methods, this type of resistance was introduced to other melons and is now patented as a Monsanto "invention". The actual plant disease, Cucurbit yellow stunting disorder virus (CYSDV), has been spreading through North America, Europe and North Africa for several years. The Indian melon, which confers resistance to this virus, is registered in international seed banks as PI 313970. With the new patent, Monsanto can now block access to all breeding material inheriting the resistance derived from the Indian melon. The patent might discourage future breeding efforts and the development of new melon varieties. Melon breeders and farmers could be severely restricted by the patent. At the same time, it is already known that further breeding will be necessary to produce melons that are actually protected against the plant virus. DeRuiter, a well known seed company in the Netherlands, originally developed the melons. DeRuiter used plants designated PI 313970 – a non-sweet melon from India. Monsanto acquired DeRuiter in 2008, and now owns the patent. The patent was opposed by several organisations in 2012.

Cutting pepper

In October 2015, the EPO has granted the Swiss seed giant, Syngenta, a patent on pepper and its use "as fresh produce, as fresh cut produce, or for processing such as, for example, canning" (EP 2 166 833 B1). The patent also covers the plants, their cultivation, harvesting and seeds. The plants have been developed to produce pepper without seeds and are derived from conventional breeding using existing biodiversity.

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

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	mutagensis	oil, plants, progeny
EP 2115147	Enza Zaden	lettuce	mutagenesis	plants, methods
EP 1261252	DuPont	sunflower	mutagenesis	plant, methods, seed, pollen
EP 1804571	De Ruiter 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 number	Company	Species	breeding method	claims
EP 1503621	Syngenta	watermelon	treeploid breeding	watermelon
EP 2114125	University of Kansas	sorghum	marker selection, genetic engineering	plants, seeds, DNA
EP 2255006	Semillas Fito	tomato	marker selection	selection
EP 1988764	Rijk Zwaan	many species	screening for discoloration, mutagenesis	screening
EP2158320	Bayer	maize	Selecting content of amylose, any method	flour and food which contains the starch
EP2173887	Biogemma	maize	marker selection	grain, usage in feed
EP 1812575	De Ruiter Seeds / Monsanto	tomato	marker selection, crossing, introgression	plants, seeds, fruits, crossing ("transfer of nucleic acid")

4.2 Case studies: patents granted on animal breeding

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).

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 with its own dairy cows.

Discussions on a patent on pig breeding (EP 1651777) that was granted in 2008 by the EPO were especially controversial. This patent was revoked after opposition from several organisations, which had collected thousands of signatures.

Another patent which was revoked after opposition concerned selection of dairy cows with improved milk quality. It also covered genetically engineered cows (EP 1330 552).

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."*

It has to be taken into account that the decision G02 / 12 and G02 /13 do also apply to animals. From a perspective of patent law, there is no difference between plants and animals.

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.

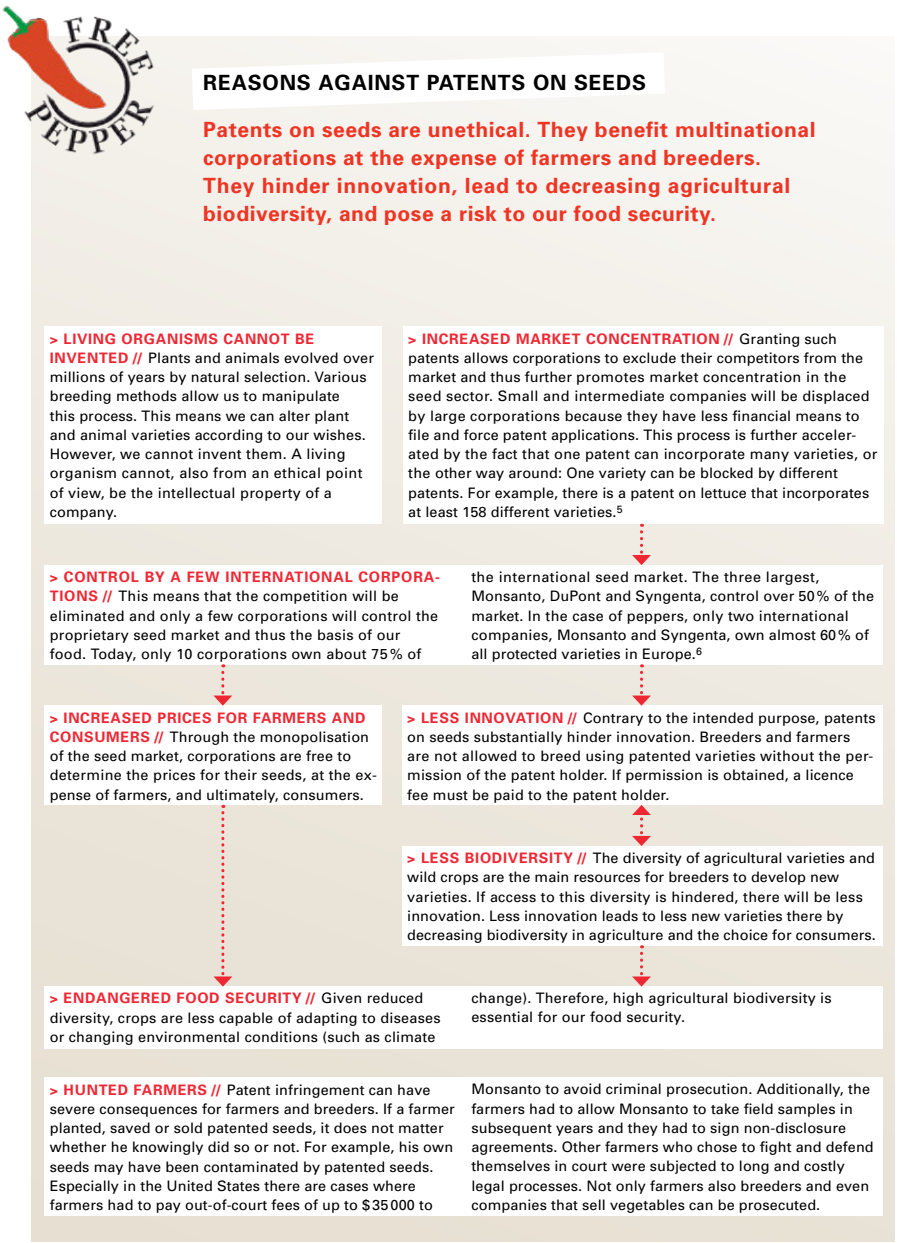

Figure 7:
Some of the consequences of patents on plants (Source: Lebrecht & Meienberg, 2014)

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.

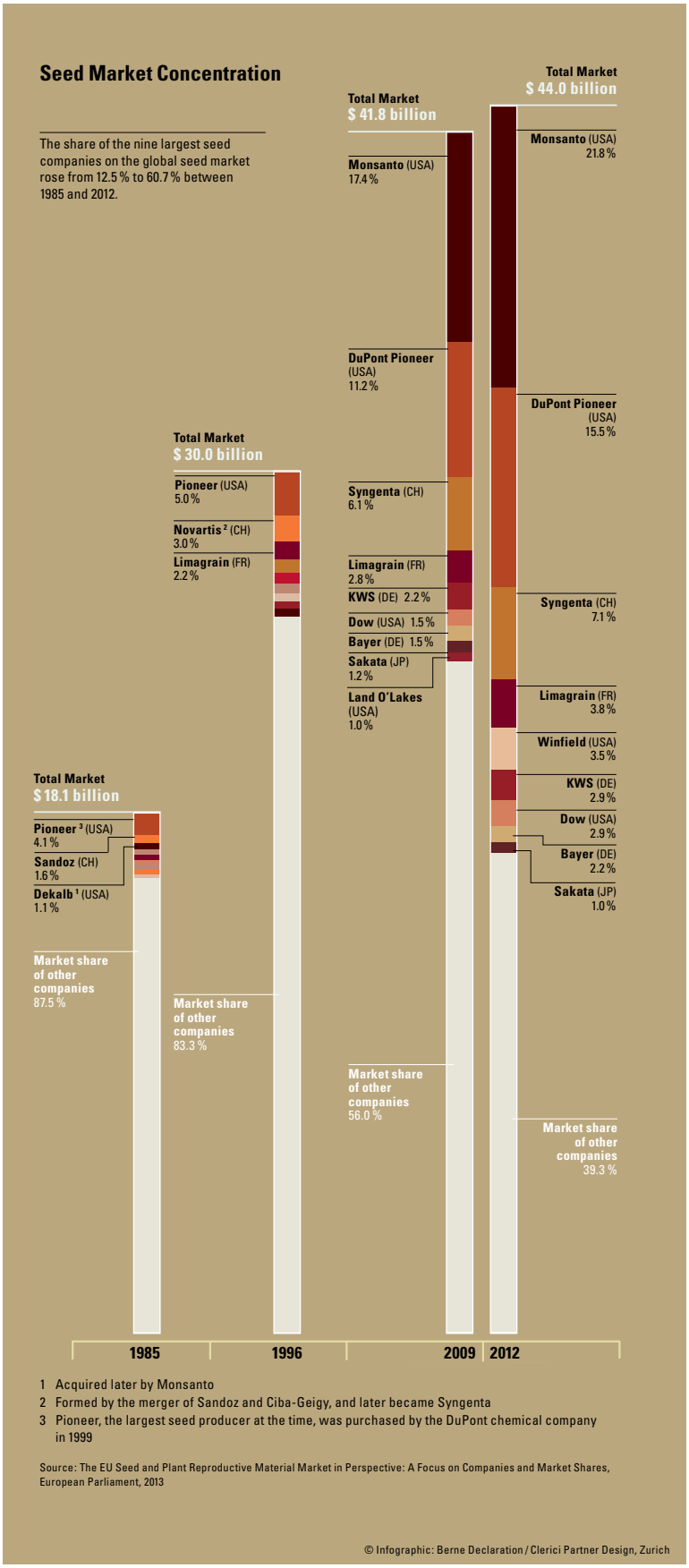

Figure 8:
Concentration in the seed market. (Source: EU Commission 2013a and Meienberg & Lebrecht, 2014)

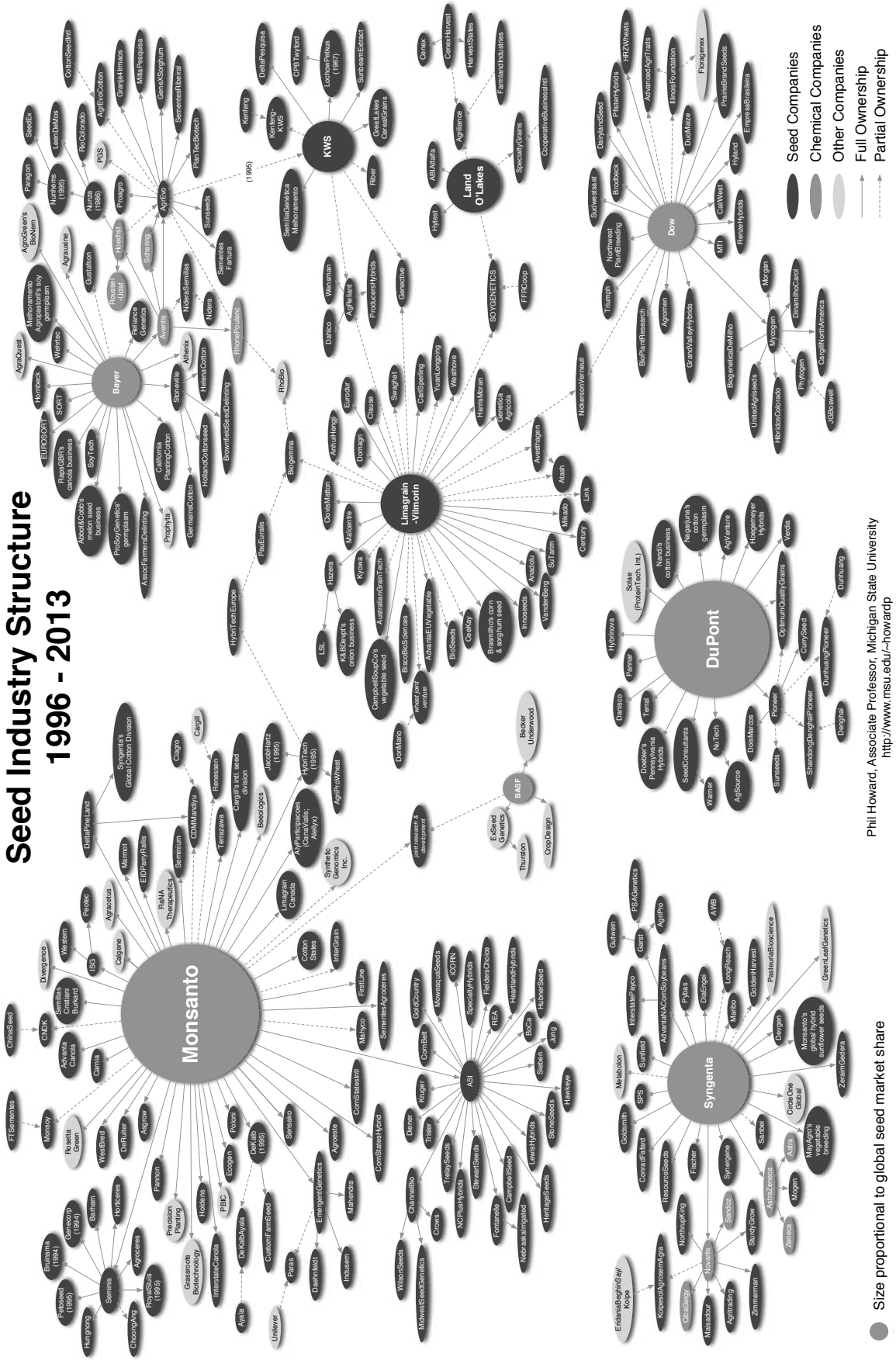

Figure 9: Global overview of market concentration driven by acquisitions made by Monsanto, Dupont, Syngenta and other corporations in recent years (source: Howard, 2013[17])

17 http://www.msu.edu/~howardp

Market 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	United States	655	14%	14%
VILMORIN (Limagrain Group)	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 reports[18], 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.

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

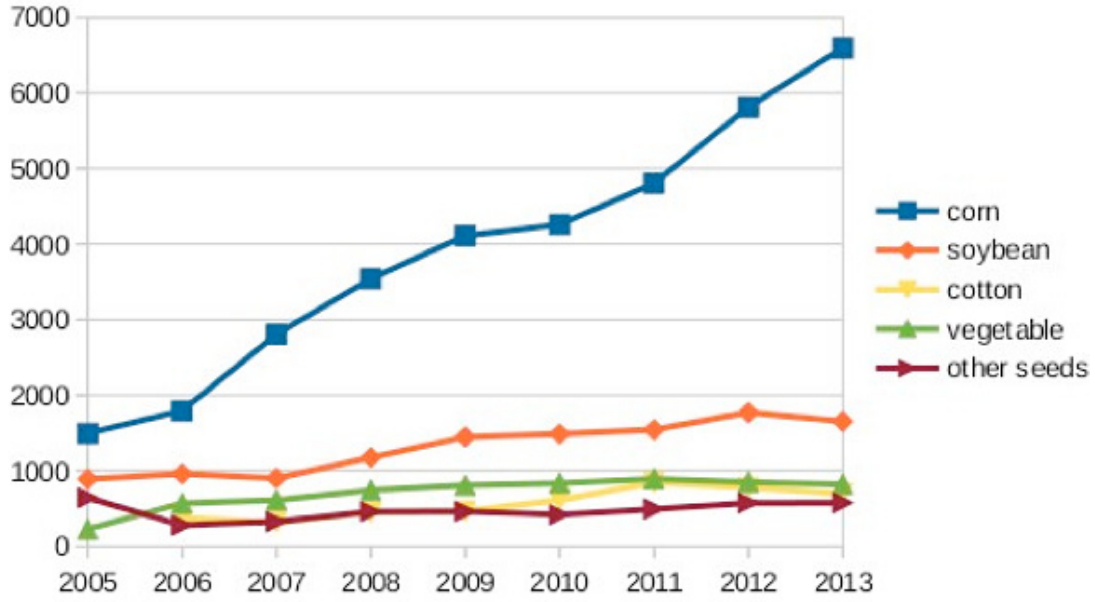

Figure 11: Net Sales (US Dollars in thousands) of Monsanto in the seed business, globally, per year. (Source: Monsanto annual reports; the figures for net sales of corn, soybean and cotton also include fees for traits of genetically engineered traits).

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)[19] According to their figures, Monsanto and DuPont/Pioneer together have a market share of 70 percent in the US corn (maize) market[20].

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).

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

20 https://www.kws.de/global/show_document.asp?id=aaaaaaaaaaffxwn

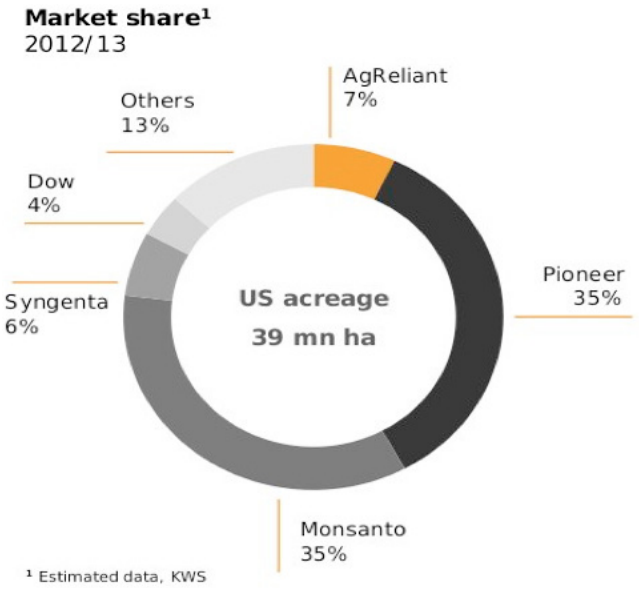

Figure 12:
Structure of US seed market for corn (maize) (source: KWS)..

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 data[21]. 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.

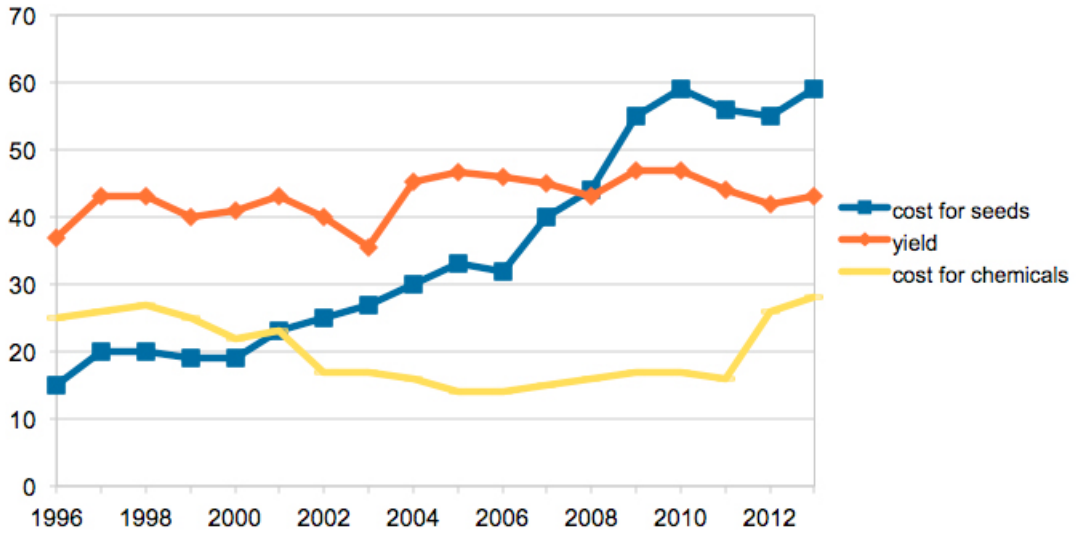

Figure 13: Development of costs for seeds (seed, US dollar per acre), costs for chemicals (chemicals, US dollar per acre) and yields (yield, bushel per acre) for soybean cultivation in the United States from 1996-2013 (source: USDA data)

21 http://www.ers.usda.gov/Data/CostsAndReturns/testpick.htm

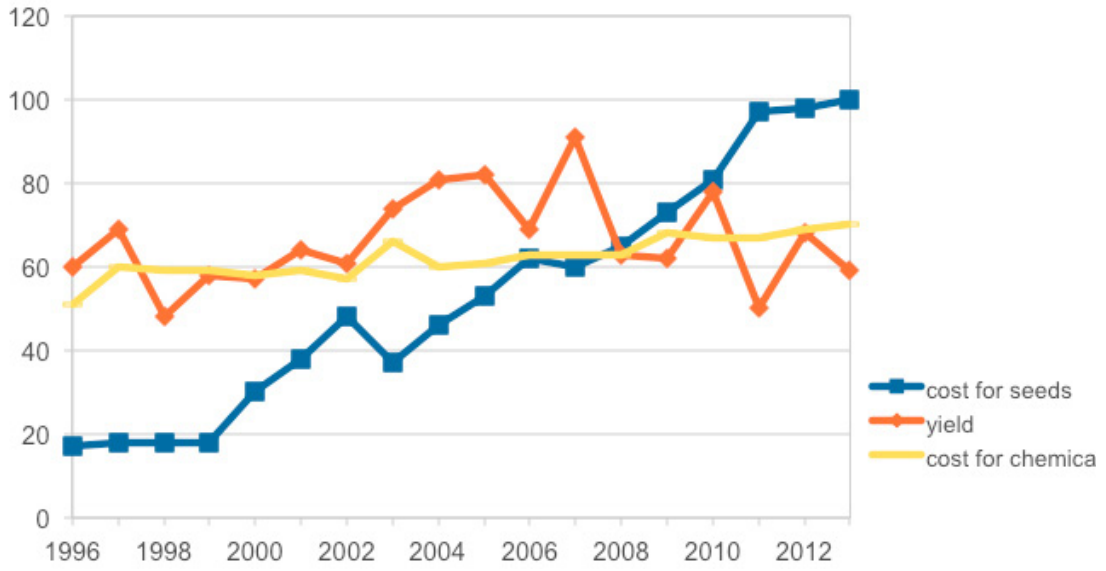

Figure 14: Development of costs for seeds (seed, US dollars per acre), costs for chemicals (chemicals, US dollars per acre) and yields (yield, pounds per acre, values equal to 10% of actual yields) for cotton cultivation in the United States from 1996 to 2013 (source: USDA data)

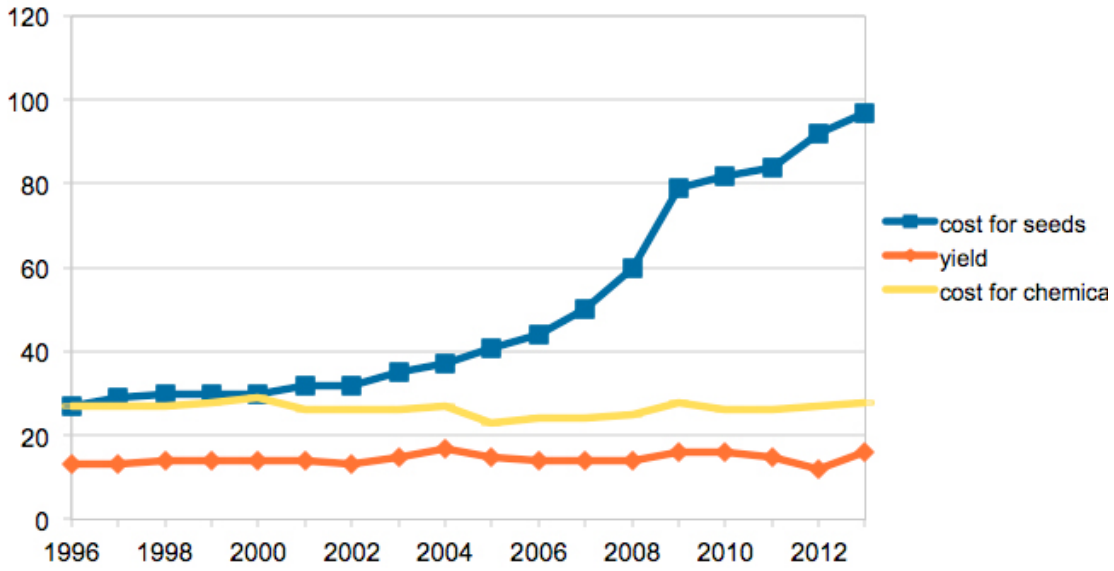

Figure 15: Development of costs for seeds (seed, US dollars per acre), costs for chemicals (chemicals, US dollars per acre) and yields (yield, bushel per acre, values equal to 10% of actual yields) for maize (corn) cultivation in the United States from 1996-2013 (source: USDA data)

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 database[22] established by European Seeds Association (ESA) has shown that 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 (...)."*

22 http://pinto.azurewebsites.net/

Patent holder	Patent number	Patent title	Species	Varieties (number)
Bejo Zaaden B.V.	NL1023179C	Brassica plants with high lebels of antivarcinogenic 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	Brassuca oleracea plants with a resistance to Albugo candida	White cabbage (Brassica oleracea L.)	1
	EP2393349	Xanthomonas campestrs pv. Campestris resistant Brassica plant and preparation thereof	White cabbage (Brassica oleracea L.)	4
Enza Zaaden 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 Rechereche 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	Cytoplamic 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
	EP2219432	Flower Pigmentation In Pelargonium Hortorum	Geraniums (Pelargonium hortorum)	1
	EP2164970	F. Oxysporum F.SP. Melonis Race 1,2 Resistant Melons	Melon (Cucumis melo)	5
	EP1973397	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 Oversees 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 vegetables[23], 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.

23 http://www.sg-vegetables.com/elicensing/about/3-overview-of-technologies

6. The way forward: the task for European politicians

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'.

Some first steps were taken already: Within the Unitary Patent, a limited breeders exemption is included. The exemption is also included in national laws of Germany and the Netherlands. The weakness of this restricted breeders' exemption is that it 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. So this limited breeders exemption can not be regarded as a final solution.

Further, Germany introduced in 2013 a change into its national patent law in Article 2 a that excludes patents on plants and animals derived from essentially biological processes for breeding. A similar wording can be found in the Netherlands. These national regulations suffer from the weakness of not having adequately defined how such a prohibition can be implemented in a way that conventional plant breeding can no longer be impeded by patents. For example criteria how to define essentially biological processes, including all relevant steps and purposes in conventional breeding as well as breeding material should be taken into account. Further it must be made sure that the protection conferred by a patent cannot be extended to plants and animals which contain the same or a similar genetic information and/ or exhibit plant characteristics as a native trait or that can be obtained by means of essentially biological processes.

The German government already announced an initiative on European level to implement a prohibition of patents on plants and animals derived from essentially biological processes for breeding. This initiative might be helpful in rendering the prohibition effective.

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) and when it is clearly stated that the protection conferred by

a patent granted on material stemming from a technical process (such as genetic engineering) cannot be extended to plants and animals which contain this information as a nartive trait or are derived by means of an essentially biological process (and express the characteristics/ function described in the patent application).

It is interesting to notice that the possibility and necessity of such a change of the implementation regulations of the EPO can also be derived from a European Parliament resolution in 2012[24]. 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. (…)"*

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, mutations, propagation without crossing) as well as all products and breeding material derived thereof, have to be excluded from patentability. Also 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 Administrative Council of the EPO adopted EU Directive 98/44 and then it became a part of the Implementation Regulation of the EPC. Therefore, this resolution from the European Parliament should also be taken into account by amending the rules of interpretation of the EPC.

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

Actions that need to be taken

The political activities so far which include changes in law as well as a strong resolution of the European Parliament, show the need and the willingness of European politicians to take further steps. As shown, 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 several ways in which European politicians can take further action:

- introducing a full breeders' and farmers' exemption into patent law and/or an mechanism for automatic licensing (licence as of right) system for breeding of plants and animals that enables non exclusive access and use of patented material.
- making a legal change to the EU Patent directive 98/44 to exclude plants and animals as well genetic resources needed for breeding.
- changing the Implementating Regulation of the EPC to reinforce the current prohibitions in European patent law.
- strengthening the existing prohibitions through a strict interpretation of the Patent Directive 98/44 by the EU.

These 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.
- 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 is very likely to be echoed in the interpretation of the EPC and EPO practice. However, the EU Commission, being under pressure from patent industry, 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. The same is true for strengthening the existing prohibitions through interpretation of the Patent Directive 98/44 by the EU: For example, the EU Commission can present an guidance for correct interpretation. In parallel, national laws could be adopted. Most of the points raised by the European Parliament could be be rectified by a change of the interpretation of European patent laws (see overview below). However, some legal ambiguity would remain as long as EU Patent Directive 98/44 does not explicitly exclude patents on plants and animals. Nevertheless, strengthening the existing prohibitions would be an important first step.

There is some dispute amongst legal experts about whether by strengthening the existing prohibitions in European Patent laws, patents on plants and animals derived from conventional breeding can effectively be excluded. But not only the European Parliament resolution as quoted above, but also national legislation and the interpretation of current laws of several contracting states of the EPC show substantial room for manoeuvre in their interpretation: In German and Dutch national law, patents on plants and animals derived from conventional breeding are already excluded, France is stating to interpret existing law in the same way.

Table 4 lists proposals that could serve to achieve more legal certainty by using the implementation regulation of the EPC as an example. These amendments of current patent law should include criteria on how to define essentially biological processes, take into account all relevant steps and purposes in conventional breeding and exclude breeding material from patent protection. It has to be made clear that technical teaching regarding the invention is taken into account as well as pre-treatment steps, unavoidable consequences and exclusive and unavoidable uses to decide whether the prohibitions apply. Further, it must be ensured that protection conferred by a patent cannot be extended to plants and animals which contain the same or similar genetic information and/ or exhibit plant characteristics such as a native trait or that can be obtained by means of essentially biological processes.

The next step would then be to reopen and amend Directive 98/44 to finally exclude all breeding processes and breeding material, plant and animal characteristics, gene sequences, plants and animals, as well as food derived thereof from patentability.

There may well be some extra steps that could be taken to resolve some of the problems. In this regard, a full breeders' exemption and / or compulsory licence as of right have to be mentioned.

A further step should aim to achieve a better balance of public interest within patent law by, for example, introducing independent jurisdiction and strengthening political control of European Patents.

Indeed, there are already several political initiatives in Europe moving in the right direction and showing quite a variation in their legal approaches. Some examples:

- In a resolution brought forward by the European Parliament on 10 May 2012 on the patenting of essential biological processes, "the European Parliament calls on the EPO also to exclude from patenting products derived from conventional breeding" (see above) [25]
- More than two million people have signed the petition urging the Administrative Council of the European Patent Organisation "to close the loopholes that allow corporations to patent plant varieties and conventional breeding methods. Clear and effective safeguards and prohibitions are needed to protect consumers, farmers and breeders from the corporate takeover of our food chain".[26]
- A breeders' exemption was introduced into the EU Unitary Patent to emphasise the importance of the PVP law and access to genetic resources in this context.
- In national patent legislation (such as in Germany and the Netherlands), some elements have already been introduced to make sure that products derived from essentially biological breeding are non-patentable.

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

26 www.avaaz.org/en/monsanto_vs_mother_earth_loc/?slideshow

- In the coalition treaty of the present German government, a European-wide initiative was announced to stop patents on plants and animal derived from conventional breeding.
- In 2015, the French Institut National de la Propriété Industrielle published a statement contradicting the G2/12 and G2/13 decisions regarding the patentablilty of products derived from essentially biological processes.[27]
- In France there are also ongoing parliamentary debates dealing with a rectification of French patent law so as to invalid patent on native traits.[28]
- The German Bundesrat in its meeting in July 2015 voted for taking actions to correct the decision of the Enlarged Board of Appeal by change of the EU Patent Directive.[29]
- In July 2015, the Dutch government took the G2/12 and G2/13 decisions to the EU AGRIFISH council, and started an initiative for a full breeders' exemption. In the protocol it is stated that "The Netherlands regretted this decision. Several member states supported the position of the Netherlands delegation, considering that this could have an impact on food production and food security, blocking innovation." [30] The Dutch government also announced an initiative during its Presidency of the Council of the European Union in first half of 2016. In August 2015, the government of Austria joined those countries that want to become active against patents on plants and animals. [31]
- in August 2015 and again in May 2016, the Austrian government announced to get active against patents on plants and animals.
- In December 2015, the EU Parliament re-emphasized its resolution from 2012.

27 http://www.inpi.fr/fr/l-inpi/actualites/actualites/article/non-brevetabilite-des-plantes-et-des-animaux-obtenus-par-croisement6130.html?cHash=560a6fdd572f246862b9c810a9cc2d37

28 See the amendment by Green Senators (link: http://www.senat.fr/amendements/commissions/2014-2015/359/Amdt_COM-350.html), which leads to the ongoing work to prohibit patents on native traits in France (link: http://www.senat.fr/compte-rendu-commissions/20150706/devdur.html#toc2)

29 http://www.bundesrat.de/SharedDocs/TO/935/to-node.html

30 www.consilium.europa.eu/de/meetings/agrifish/2015/07/13/

31 www.bmvit.gv.at/presse/aktuell/nvm/2015/0813OTS0138.html

Table 4: Proposals for strengthening current prohibitions of European Patent law to meet the requirements of the European Parliament resolution of 10 May 2012 (2012/2623(RSP)) 32, by using the Implementation Regulation of the European Patent Convention (EPC) as an example. [32]

Existing implementation regulation of the EPC[33]	Proposed additions	Comments
Rule 26 (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 in addition to 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.[34]	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
Rule 26 (5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.	A process for the production of plants or animals is essentially biological if it consists of processes such as crossing, multiplication or selection. Breeding processes that rely on the use of whole plants or part of plants (cells, leaves, cuttings) or crossing of whole genomes for introducing new traits into plants, and do not require the insertion of material prepared outside the cells should be considered to be essentially biological in the meaning of patent law. Products obtained, or that can be obtained, by means of conventional breeding, all methods and steps 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. The protection conferred by a patent cannot be extended to plants and animals which contain the same or a similar genetic information and/or exhibit plant characteristics as a native trait or that can be obtained by means of essentially biological processes.	This is in line with the resolution of the European Parliament, demand Nr. 4

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

33 http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/$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

34 see Dolder, 2007

7. 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. At the same time patent system moved away from one which promotes innovation in the interests of society at large.

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, the existing prohibitions have to be strengthened 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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Annex 1

Legal considerations that have to be taken into account in the upcoming clarification of the scope and interpretation of Directive 98/44/EC (Art. 4) and Article 53 (b) of the European Patent Convention

Technical analysis provided by *No Patents on Seeds!*, February 2016, www.no-patents-on-seeds.org

Summary

Within the framework of the upcoming legal clarification requested by the European Parliament, particularly in regard to the exclusions in Article 4 of Directive 98/44/EC (corresponding to Art 53 (b) of the European Patent Convention (EPC)), the EU Commission as well as the Member States of the EU and the European Patent Organisation should at minimum clarify that:

- The definition of essentially biological processes encompasses all relevant steps and purposes in conventional breeding.
- Patents granted on plant or animal-related inventions do not cover plants or animals or plant and animal varieties (races) derived from conventional breeding, nor with plant or animal characteristics, and their genetic components that can be derived from conventional breeding or are existent in native traits,
- The whole content approach is applied. Thus, the technical teaching regarding the invention is taken into account as well as pre-treatment steps, unavoidable consequences and exclusive and unavoidable uses to decide whether the prohibitions of Art. 4 (Directive 98/44) or Art. 53 (b) (EPC) apply.

In conclusion, it has to be made clear that in the area of conventional breeding all breeding processes and breeding material, plant and animal characteristics, gene sequences, plants and animals, as well as food derived thereof are excluded from patentability.

1. Introduction

In its Resolution of 17 December 2015, the EU Parliament requested the EU Commission *"as a matter of urgency, to clarify the scope and interpretation of Directive 98/44/EC, and in particular Articles 4 12(3)(b) and 13(3)(b) thereof, in order to ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes, and to clarify that breeding with biological material falling under the scope of a patent is permitted."*

While Article 4 of the Directive deals with prohibitions in patent law regarding plant and animal breeding, Articles 12(3)(b) and 13(3)(b) pertain to compulsory cross-licensing, which is why the EU Parliament has further requested the EU Commission "to clarify that breeding with biological material falling under the scope of a patent is permitted." This can be achieved by several measures, one of them includes the establishment of a full breeders' exemption as established under the plant variety protection system.

Article 4 is partially identical with the content of Article 53 (b), EPC and deals with the prohibitions in patent law regarding plant and animal breeding. The wording of the article is:

1. The following shall not be patentable:
   a. Plant and animal varieties;
   b. Essentially biological processes for the production of plants or animals.
2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Even before this recent resolution was passed, the European Parliament had already been urging the European Commission *"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"* and requested *"the so-called whole content approach"* to be applied to the interpretation of current provisions in European patent law *(EP Resolution on the patenting of essential biological processes, 10 May 2012 (2012/2623(RSP))*.

This document sets out a possible legal interpretation that would allow the European Commission as well as the Member States of the EU and the European Patent Organisation to come to a meaningful clarification in regard to the existing prohibitions. The document takes into account the history of patent law into account, and aims to provide legal expertise to ensure effective and meaningful exclusions from patentability, including but not limited to the 'whole content approach'. If the Commission and the EU Member States do not share these legal considerations, the way forward will be to find another consequential and coherent way "to exclude from patenting products derived from conventional breeding and all conventional breeding methods". In any case, the solution has to be so robust that it cannot easily be negated or circumvented by clever wording of the claims or other means.

2. Taking the history of European patent law and the European Patent Convention into account

Contrary to the opinion of some experts, there is no legal obligation under the European Patent Convention (EPC) that requires the granting of patents on plants and animals. It is important to be aware of this legal situation since it is decisive for the history and interpretation of EU Directive 98/44.

Indeed, to some extent, the European Patent Office (EPO) was already granting patents on plants before the introduction of genetic engineering and the Directive. There is, however, no indication in the wording of the European Patent Convention (EPC) adopted in 1973 that the legislator at that time intended to allow patents on plants and animals in general.

A historical examination including legal comments published during the first fifteen years after the EPC came into force, shows that, for example, standard commentaries (such as well-known commentaries by Benkard, Patentgesetzkommentar, 8. Auflage 1989, Beck; Schults Patentgesetzkommentar, Heymanns, 2. - 4. Auflage, 1987; Singer, Europäisches Patentübereinkommen, 1989, Heymans) came to the conclusion that in general, plants and animals were not patentable.

The same conclusion can be drawn from legislation passed by Contracting States when the EPC was transposed into national legislations. In Switzerland, for example, in 1976 when national patent law was adopted, the Swiss Bundesrat made a statement clearly showing that plants and animals were regarded as non-patentable: "([Es] können nicht patentiert werden: auf dem Gebiet des Pflanzen- und Tierreichs: die Lebewesen selbst."). A similar comment can be found in the German Bundestagsdrucksache Nr. 8/2087 of 7 September 1978, which concerns the interpretation of German patent law.

Despite this legal framework, the EPO granted some patents on plants in the 1980s and 1990s. It appears that at least some examiners at the EPO believed - contrary to the references above – that patents on plants could be granted. As decisions T 356/93 and T1054/96 show, this question was still not settled when Directive 98/44 was adopted.

The oppositions and appeals against the patent on the oncomouse (which was the first patent on a mammal in Europe), T0315/ 03 and decision G1/98 (genetically engineered plants) were finally decided after the EU Directive was adopted and had become part of the Implementation Regulation of the EPC. Thus, G1/98 and T 0315/03, which can be seen as precedent cases in this field, cannot be interpreted as decisions made independently of the wording of the EU Directive. It was the EU Directive 98/44 that paved the way for a new interpretation of the EPC and was used by the EPO to grant patents on genetically engineered plants and animals.[35]

To summarise, the question to which extent plants and animals are patentable under the EPC was not finally decided until the EU Patent Directive 98/44 was adopted and taken into the Implementation Regulation of the EPC. The EPC as adopted in 1973, however, cannot be interpreted to mean that patents on plants and animals were generally allowed. It was only after the EU Directive was adopted and became part of the Implementation Regulations that the EPC was applied as it is currently.

In conclusion, the current interpretation of the EPC could be changed to exclude patents on plants and animals - at least, those derived from conventional breeding - without coming into conflict with the original intention of the EPC.

3. Exceptions to Patentability: Article 4 of EU Directive 98/44 and Article 53 (b) of the EPC

3.1 The context of Article 4

To clarify the scope of Article 4, it has to be put in context. As the title of the Directive 98/44 (Legal Protection of Biotechnological Inventions), and the wording of the Recitals 52 and 53 of the Directive show, it was not the legislator's intention to allow the patentability of products obtained from essentially biological processes. It should be noted that at the time when the Directive was being discussed and voted on in the EU Parliament, the European Patent Office (EPO) had officially stopped granting patents on plants and animals because of decision T356/93 made in 1995. Thus, in adopting Directive 98/44 members of the Parliament, as well as the EU Member States and the EU Commission paved

35 It should be noted that also the EU Directive does not explicitly request patents on plants and animals, but only on "inventions which concern plants or animals".

the way for harmonised patent protection intended only for plant-related inventions in the context of genetically engineered plants and animals. Indeed, the EU Directive led to a significant shift in current practice at that time. It was only after the Directive was adopted and had become an integral part of the new Implementation Regulations of the EPC in 1999 by a decision of the Administrative Council of the European Patent Organisation that the EPO resumed granting patents on plants and animals derived from genetic engineering.

It can be assumed that when adopting the Directive 98/44 the legislator did indeed regulate patents on plant-related inventions stemming from genetic engineering. At the same time, there is nothing to indicate that the legislator generally wanted to allow patents on plants and animals derived from essentially biological processes used in conventional breeding.

It can be concluded, that all processes in conventional breeding, as well as all products (plants, animals, their characteristics, their genetic components, seeds, breeding material, gene sequences) are excluded from patentability under Directive 98/44.

3.2 The meaning of Article 4

Article 4 (1) of the EU Directive as well as Article 53 (b) of the EPC prohibit patents on *"plant and animal varieties and essentially biological processes for breeding"* (Article 4 (1)).

On the other hand, patents can be granted on inventions concerning plants or animals i*f the technical feasibility of the invention is not confined to a particular variety*. This is the first exemption from the exclusions and is discussed in the following paragraphs in the context of the prohibition relating to plant and animal varieties (Article 4 (2)).

Inventions which concern a microbiological or other technical process or a product obtained by means of such a process can be patented. This second exemption from the exclusions is discussed in the following paragraphs in the context of the prohibition relating to essentially biological processes for breeding (Article 4 (3)).

Plant varieties

As aforementioned, Article 4 (1) (a) prohibits patents on plant varieties while Article 4 (2) allows patents on inventions concerning plants or animals if the technical feasibility of the invention is not confined to a particular variety.

This exemption from the exclusion (Art 4 (2)) provides the main justification for the European Patent Office (EPO) to currently grant patents on plants and animals derived from genetic engineering. Art 4 (2) is part of the Implementation Regulation of the European Patent Convention (Rule 27 (b)). This legal approach was used in the G1/98 decision made by the Enlarged Board of Appeal, which is seen as the precedent case for the patenting of genetically engineered plants and animals under the EPC, ruled upon shortly after the inclusion of the EU Directive 98/44 in the Implementation Regulation of the EPC.

In the field of conventional breeding, the exemption from the exclusion (Art 4 (2)) cannot be used to allow patents on all plants and animals for several reasons:

1. As a general rule, this exemption cannot be applied to conventional breeding, since the whole rationale of the EU Directive is directed to "biotechnological inventions" and thus to the field of "genetic engineering" (see point above).
2. If the "technical feasibility" (which should not be confined to a particular plant variety to fall under patent protection) is put in context of the processes for genetic engineering, which enables the transfer of DNA sequences, for example, beyond the boundaries of species, the exemption from the exclusion (Art 4 (2)) develops a specific meaning. However, in conventional breeding most plant characteristics can be transmitted to any other variety within the same species, just by further breeding, without using a specific technology. As a result, the criterion retained in Article 4 (2) and applied by the EPO to restrict the exception to patentability, does not have a specific technical meaning and does not provide any legal clarity in the context of conventional breeding. To summarise, from a technical point of view, the criterion of "confinement of the technical feasibility of the invention to a particular plant or animal variety" can hardly be applied in the field of conventional breeding.
3. There are further technical and legal differences between plants derived from genetic engineering and those derived from conventional breeding. These differences relate to the concept of a plant variety. According to the EPC, Rule 26 (4) (a) a plant variety (which is not patentable) is "*defined by the expression of the characteristics that results from a given genotype or combination of genotypes."*
   This definition is equivalent to the one used in plant variety protection system (PVP).
   This definition was applied by the EPO in its precedent decision G 1/98 by implementing the content of Article 4 (2) EU Directive 98/44. The decision concerns a genetically engineered plant produced by Novartis. In this decision, plant varieties with characteristics that are based on a genotype (a specific combination of genetic conditions) were regarded as not patentable. On the other hand, plant characteristics, that are defined by a single DNA sequence and can be transferred to other plants by technical means, are regarded as being patentable (even if plant varieties fall within the scope of the patent). For example, a genetically engineered plant which has had a gene inserted into its genome in order to make it herbicide resistant would not be a plant variety, as such plant grouping would not be defined by its whole genome, but rather by an individual characteristic linked to a specific defined and inserted DNA i.e., the herbicide resistance.
   But these criteria cannot be applied in the same manner to plants derived from conventional breeding as to genetically engineered plants: Many of the relevant plant characteristics described in patents on plants derived from conventional breeding, are not based on a single DNA sequence, but upon a combination of genetic conditions. For example, characteristics described as Quantitative Trait Locus (QTL) vary in degree and can be attributed to polygenic effects. In several patents, plants are simply described by their phenotype, traits and plant characteristics, without any details about a specific gene sequence. As a result, the characteristics of these plants cannot be described as being "defined by a single DNA sequence". Therefore, based on the criteria used in Directive 4.2 and in G1/98, no patents can be granted on plants or animals derived from conventional breeding.

4. In general, the overlap between plant variety protection and patent protection is much stronger in the context of conventional breeding in comparison to patents granted in the field of genetic engineering. In conventional breeding, the plant characteristics are no longer defined by an isolated gene sequence, but in many cases by interactions within a genotype. Thus, in the context of conventional breeding, patents will largely overlap with the concept of plant variety protection. It is evident, that if the provisions of Article 4 (2) are applied to plants derived from conventional breeding in the same way as to genetically engineered plants, the prohibition of patenting plant varieties would become meaningless and the PVP system would lose its function. Consequently, no patent protection should be given to any plants or animals nor their characteristics, breeding material, gene conditions that can be derived from or be used in conventional breeding.

To summarise, if the provisions of Article 4 (2) are applied to plants derived from conventional breeding in the same way as they are applied to genetically engineered plants, the prohibition of patenting plant varieties will become meaningless. In this case, patents will also be granted on plants if:

- they show characteristics that are based on a genotype and not only single DNA sequences,
- they have characteristics that can be transferred easily to other plant varieties by crossing and selection and do not require technical means that can overcome the barrier between species.

As a result, plants and animals derived from conventional breeding cannot and should not be regarded as patentable under Article 4 (1) (a) and Article 53 (b).

Essentially biological processes

The definition of what is an essentially biological process is difficult to understand from the provisions of the Directive. Article 2 (2) reads:

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

As the decisions G2/07 and G1/08 of the Enlarged Board of the EPO show, this definition needs further interpretation before it can be applied in practice. Therefore, the EPO chose to formulate its own definition which 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" (…)."

This definition raises several questions:

- Is this definition sufficient to exclude all relevant processes used in conventional breeding?
- 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?

Essentially, the EPO decision created some grey areas. Neither is the definition chosen by the EPO ("A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection") very convincing. Thus, the EU Commission as well as Member States of the EU and the European Patent Organisation need to put forward a clarification that is precise and comprehensive, acting in accordance with the rationale of the Biotech Directive to solely apply to patents linked to genetic engineering, and also respecting the political requests from, for instance, the aforementioned 2012 and 2015 resolutions adopted by the EU Parliament.

So, how to define essentially biological processes? The decisive criteria are not clearly defined. Nevertheless, it is important to understand that in the meaning of patent law the word biological is not used as a synonym for *natural or organic* and does not have specific scientific meaning within biology. Rather it seems to be characterised by the level of human intervention. This in itself raises further problems: In biology one could make a simple distinction between those processes that can be regarded as *biological* in the sense that human intervention is not necessary and those processes that are *technical* and would not occur without human intervention. But in the context of Article 4 (1) (b), these simple categories cannot be applied: Breeding per se cannot in any way occur without human intervention. Nevertheless, within breeding there are processes that are regarded as essentially biological.

So what processes are patentable, which are not? If one looks at the history of Directive 98/44, it is evident that this Directive would not exist without the new methods of genetic engineering. This technology has allowed direct and specific technical intervention on the level of the genome and not only – as in conventional breeding - on the level of the whole organism, parts of the plants, or the whole cells. Thus, the ability to isolate and transfer specific genetic information by technical processes can be regarded as the decisive criterion for the meaning of the Directive 98/44 to allow a distinction between "essentially biological" (as being not technical, not patentable) in Article 4 (1) (b) and "technical" (as not being essentially biological, and patentable) in Article 4 (3).[36]

In conclusion, in order to ensure that the Biotech Directive remains true to its rationale, coherent and truly prevents the extension of patent protection to conventional breeding efforts, all exemptions to the exception to patentability of Article 4 (1) should be read in a contextualised way, thereby precluding the application of the "confinement" and "technical feasibility" criteria to conventional breeding, and that the concept of "essentially biological" be more clearly defined, with reference to the ability to isolate and transfer specific genetic information through technical processes.

36 In this context, it is also important to understand the role of inventions which concerns a "microbiological process" (Article 4 (3)). The term microbiological process has some history in patent law. Several patents were granted by the EPO in the 1990s with the reasoning that genetically engineered plants and animals can be regarded as being derived from microbiological processes. This argumentation was used by the EPO to overcome the exclusion of plant and animal varieties from patentability. However, with the decisions T356/93 and G1/98, there was a change in the legal interpretation. For example, in G1/98 it is stated that genetically-modified plants should not be treated as products of microbiological processes. As a result, the term "microbiological process" cannot be used to allow patents on plants derived from conventional breeding, even if parts, cuttings or cells are used within the process of breeding.

4. How to effectively exclude essentially biological processes for breeding

If essentially biological processes are defined, the definition should be comprehensive, applicable in practice and flexible enough to encompass technical future development. From a technological point of view, two basic categories can be distinguished:

- Techniques that directly interfere with the plants and animals on the level of their genome (such as transgenic plants, gene-editing) and
- Processes based on the usage of the whole genome, cells or plants (such as MAS, random mutagenesis, protoplast fusion).

Using the second category as a definition for essentially biological processes within the meaning of patent law puts this definition into a meaningful technical context, leaving enough flexibility to evolve further. The term "conventional breeding" could be used synonymously in this context. Against this background, the following definition of essentially biological is applicable, meaningful and legally coherent:

> *"Breeding processes such as crossing, multiplication or selection that rely on the use of whole plants or parts of plants (cells, leaves, cuttings), or on the crossing of whole genomes, and do not directly and specifically interfere with the plant and animals on the level of their genome, shall be considered as essentially biological in the meaning of patent law".*

In order to ensure a legally sound and effective exclusion of essentially biological processes from the realm patentability, this paragraph should be included in the legal interpretation to be provided by the European Commission, and subsequently be integrated into national patent laws as well as the Implementation Regulation of the EPC.

5. How to effectively exclude products derived from essentially biological processes

There are four points that are of general relevance in this context, three of them have already been mentioned:

1. Products derived from essentially biological processes (in this case plants, animals, seeds, fruits etc.) have to be exempted from patentability to render the prohibition in Article 4 (1) (b) of the Patent Directive and Article 53 (b) of the EPC effective. Disregarding the process exclusion in the examination of product claims altogether would have the general consequence that for many plant breeding inventions patent applicants and proprietors could easily overcome the process exclusion of Article 4 (1) (b) of the Patent Directive and Article 53 (b) of the EPC by relying on product claims providing a broad protection which encompasses that which would have been provided by an excluded process claim (see Technical Board of Appeal of the EPO in its interlocutory decision of 31 May 2012, case T1242/06). As a result, the prohibition of Article 4 (1) (b) of the Patent Directive and Article 53 (b) of the EPC could no longer be applied in a meaningful way because the effectiveness of the prohibition regarding the breeding process is dependent on the exclusion of products derived from such processes.
2. As mentioned, the technical distinction between varieties and patentable plant-related inventions as established in the context of genetically engineered plants (G1/98 and Article 4 (2)) cannot be applied the same way in conventional breeding.

3. Because the potential overlap between plant variety protection law and patent law is much stronger in conventional breeding in comparison to genetic engineering, the distinction between the two legal systems also has to be enforced.
4. It is important to understand the meaning of what is called *absolute product protection*. This means in general, that any product that bears the characteristics that are described in a patent will fall under the scope of the patent, no matter which processes are used to produce it. This has huge consequences in the context of plant and animal breeding: If a patent on a plant is described by referring to a specific process, the scope of the patent is not limited to this process but covers all plants with the same characteristics (or traits). As a consequence, the scope of the patent could even cover plants or animals that existed before, but were previously not known to show the characteristics as described in the patent. There are many plant and animal characteristics that can be introgressed into plants or animals by genetic engineering, as well as by conventional breeding. The biotech companies know this and use it to intentionally circumvent the prohibitions: Case law shows in several instances that the description of the process is mostly technical (based on genetic engineering or gene-editing), preventing the activation of the exception to patentability, but that the characteristics actually claimed by the patent are much more likely to be achieved by conventional breeding.

In light of these findings, the following clarifications should be made by the EU Commission as well as the Member States of the EU and the European Patent Organisation:

> *"Products obtained, or that can be obtained, by means of conventional breeding, all methods and steps used in conventional breeding, including such as SMART breeding (precision breeding) as including breeding material and genetic conditions used for or produced by conventional breeding shall be excluded from patenting under Article 4 (1)".*
>
> *"The protection conferred by a patent cannot be extended to plants and animals or plant and animal varieties which contain the same or a similar genetic information and/ or exhibit plant characteristics resulting from a native trait or are obtained or can be obtained by means of essentially biological processes."*

The first paragraph of the above should be integrated into national patent laws as well as the Implementation Regulation of the EPC, while the second paragraph concerns only national patent laws (which deal with the scope of protection).

In addition, to make sure that no plant characteristics are claimed that can be obtained by conventional breeding, it should be made explicit that the patent holder has the burden of establishing the proof.

6. How to apply the whole content approach

It is a well-known problem in the practice of the EPO that clever wording of claims can allow a patent applicant to circumvent the prohibitions set out in Article 4 (Article 53 (b) of the EPC). For example, if a plant variety in the claims of a patent application is just described by some plant characteristics, the EPO might grant the patent despite the fact that it is targeting plant varieties. For example, patent EP 1597965 ("severed broccoli") claims a plant which under US Patent law is described as a variety while at the EPO it is described just by plant characteristics. It was granted by the EPO in 2013.

The problem created by clever wording of the claims, which can lead to the circumvention of prohibitions in patent law, is similarly problematic in regard to Article 6 (2) (c) of the EU Directive which excludes "uses of human embryos for industrial or commercial purposes". In the decision G2/06 of the Enlarged Board of the EPO, this problem was resolved by referring to the so-called whole content approach. It requests that in assessing inventions and patent applications under the exclusion provisions, the whole content of the specification of the patent application has to be considered in addition to the claims in order to decide if the exclusions are applicable. This approach was confirmed by the European Court of Justice (C-34/10).

In general, the description, drawings and claims of a European patent application constitute a unit which cannot be divided up in order to evaluate the patentability of inventions under Articles such as those concerning inventiveness, novelty and disclosure (Articles 52 to 57 and Articles 82 to 85 EPC).[37]

As aforementioned, the application of the "whole content approach" to the provisions regarding plant and animal breeding was requested by the EU Parliament in its resolution of 2012. The EU Commission should follow this approach for additional clarification. Therefore, the following wording should be used to establish new rules for the interpretation of Article 4 of the Directive and Article 53 (b) of the EPC, and thereby achieve more legal certainty and fulfil the request made by the European Parliament:

> *The description, drawings and claims of a European patent application constitute a unity which cannot be divided for evaluating the patentability of inventions under Article Art. 4 of Directive 98/44 and Article 53 (b), EPC. Accordingly evaluation of the patentability of inventions shall be based on the whole content of the European patent application, not on separate claims.*
>
> *Exclusion of inventions from patenting under Art. 4 of the EU Directive 98/44 and Article 53 (b), EPC shall not be circumvented by purposive drafting of the claims of patent applications.*
>
> *Technically unavoidable pre-process steps and technically unavoidable post-process steps and/or unavoidable post-process uses of the products shall constitute part of the invention, even if they are not explicitly disclosed in the specification and/or the claims of a patent application.*

This provision should also be integrated into national patent laws as well as the Implementation Regulation of the EPC.

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37 For further information see presentation of Professor Dolder at the hearing in legal committee of the German Bundestag, 11 May 2009, http://webarchiv.bundestag.de/cgi/showsearchresult.php?filetoload=/srv/www/htdocs/archive/2009/0508/ausschuesse/a06/anhoerungen/53_Biopatent/04_Stellungnahmen/Stellungnahme_Dolder.pdf&id=1106

Annex 2

Why the Swiss Compulsory Licence is not a solution for the problems related to patents on seeds.

Technical analysis provided by *No Patents on Seeds!,* May 2016, www.no-patents-on-seeds.org

Introduction:

In the discussions on the patentability of products derived from essentially biological processes and native traits, some stakeholders (esp. from the industry) have put forward the notion that a compulsory licence as enacted in Swiss patent law could be a solution to the problems related to patents on seeds. It appears that this kind of solution may have been has been proposed to avoid any change in the law linked to the question of patentability or the interpretation of such laws. Stakeholders in favour of this solution do not seem to want any changes at all regarding the patentability of plants derived from essentially biological processes. All the controversial patents such as those on broccoli and tomato and more generally on breeding material, plant characteristics, gene sequences, seeds, plants and fruits could still be granted in the future.

This so-called solution might give the impression that the impact of patents on seeds can be mitigated. But taking a closer look, the introduction of such as system would mostly serve the interests of those stakeholders who are hoping to profit from the granting and exploitation of patents. Undoubtedly, from the perspective of broader public, this approach will hamper future plant breeding through legal uncertainties and increasing costs. Furthermore, this approach completely fails to address the problems of animal breeding.

1. The Swiss law:

Since 2008 Art.36a of the Swiss patent law is in force:

Art. 36a. Dependent rights / II. Dependent plant variety rights

II. Dependent plant variety rights

1 When a plant variety right may not be claimed or used without infringing an earlier-granted patent, the plant breeder or the owner of the plant variety has the right to a non-exclusive licence to the extent required to obtain and use his plant variety right, provided that the plant variety represents an important advance of considerable economic significance in comparison to the patent-protected invention. For varieties for agriculture and food, the criteria under the Seed Ordinance of 7 December 1998 serve as a reference point.

2 The proprietor of the patent may make the grant of a licence conditional on the owner of the plant variety granting him a licence to use his plant variety right in return.

This article has to be read together with Art. 40e of Swiss patent law, which sets out the framework for obtaining a licence according to Art. 36a:

Art. 40e. Common provisions for Articles 36-40d

I. Common provisions for Articles 36-40d

1 The licences provided for in Articles 36-40d are granted only if efforts by the applicant to obtain a contractual licence on appropriate market terms within a reasonable period of time have been unsuccessful; […]. Such efforts are not required in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

2 The scope and term of the licence are limited to the purpose for which it has been granted.

4 The licence is primarily granted for supplying the domestic market. […]

5 The proprietor of the patent has the right to appropriate remuneration. In assessing the remuneration, the circumstances of the individual case and the economic value of the licence are taken into account. […]

6 The court shall decide on the grant and revocation of licences, on their scope and duration as well as on the remuneration payable. In particular, it shall revoke an entitled person's licence on request if the circumstances that led to its being granted no longer apply and it is not expected that they will arise again. Appropriate protection of the legal interests of the entitled person remains reserved. […]

The basis of the draft for Art. 36a is Art. 12 of the EU Biotech Directive:

Article 12 of EU Directive 98/44

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

Reading Para. 52 of the preamble of the Biotech Directive, which has similar wording, it seems that Art. 12 was drafted to access products from genetic engineering. (This shows, as do many other parts of the Biotech Directive, that it is intended to cover patents based on genetic engineering and not products based on conventional breeding):

(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;

2. Benefits and Shortcomings of Art. 36a

The main difference between the EU Directive and Art. 36 of Swiss patent law is the clarification that for the interpretation of the *"important advance of considerable economic significance" "the criteria under the Seed Ordinance"* has to be taken into account as a *"reference point"*. This was an attempt to counter the fact that the current wording in the Biotech Directive hardly makes any sense if a court has to compare a patented invention (e.g. a plant with a trait for herbicide tolerance) with a plant variety (including this patented trait). It is like comparing apples to oranges[38]. It is just impossible to pretend that a variety including a patented trait *"constitutes significant technical progress of considerable economic interest"* compared with the patented trait itself. It is therefore not surprising that Art. 12 of the Biotech Directive has never been used by breeders. Art. 36a of the Swiss patent law provides some guidance on comparison by clarifying that the criteria under the Swiss Seed Ordinance should be taken into account when considering if a variety is an "important advance of considerable economic significance". The criteria under the Swiss Seed Ordinance referenced could only be the Criteria in Art. 5 of the Ordinance.

Article 5 of the Swiss Seed Ordinance:

Art. 5 conditions for admission[39]

1 A variety is entered in the catalogue of varieties if:

[…]

b .it brings, compared to the other varieties, an improved value for the cultivation or use;

This criteria is valid for field crops but not for vegetables or other species or varieties of lesser importance. But nowhere is the meaning clarified in regard to when this criteria should be used as a reference point. A different wording of Art. 36a, which would have made clear that all varieties entered in the catalogue have a right to receive a licence under Art. 36, was rejected in the parliamentary discussion of the Swiss patent law revision. But, as shown in the following, even if this had been accepted, most of the relevant problems would not have been resolved.

Taking into account the existing legal basis and the current problems breeders and farmers have in accessing patented plants, the following shortcomings of Art. 36 in the Swiss patent law are apparent:

1. Art. 36a failed to provide factual proof that it could resolve the problems experienced by breeders and farmers. So far, no non-exclusive licences in accordance with Art. 36a have been granted, where a court had to interpret the *"important advance of considerable economic significance"* taking into account the *"the criteria under the Seed Ordinance"* as a "reference point". It is simply not used. Therefore, there is no jurisprudence and no clarity on how these terms could be interpreted. Legal uncertainty remains if a certain variety fulfills the criteria under Art. 36a. However, legal certainty is exactly what breeders need most.
2. Even if a breeder were to receive a licence after a court decision, such a licence would only be valid

38 The heart of the problem is that the wording in the Biotech Directive is a copy-paste from the TRIPS Agreement Art. 31l, which regulates the exploitation of a patent ("the second patent"), which cannot be exploited without infringing another patent ("the first patent"). But comparing two patents is different to comparing a patent and a plant variety. And, therefore, other terms for the granting of these kind of licences should have been developed.

39 Own translation

for the country where the court decision was made. In reality, even small and medium breeders often sell their varieties in several countries. In this case, they would have to fight for a licence in each country where the patent is valid if they wanted to sell their varieties elsewhere.
This is also true in the case of future unitary patents. The preamble of REGULATION (EU) No. 1257/2012, implementing enhanced cooperation in the area of the creation of unitary patent protection clarifies in para 10 that: *Compulsory licences for European patents with unitary effect should be governed by the laws of the participating Member States as regards their respective territories.* This means that jurisprudence and court decisions in different countries could diverge, and, therefore, increase legal uncertainty.

3. In Switzerland and in the EU, this kind of license will only be granted if the applicant has plant breeders' rights in the respective country on the specific variety. There are many examples where breeders and farmer-breeders decide not to apply for plant breeders' rights. In such cases, the law is not applicable.
4. The scope of the licence would be restricted to a specific variety. If a breeder has included the patented "invention" in several breeding lines resulting in various varieties, he has to negotiate licences (or fight for them in court) for each variety.
5. All subsequent breeders, using the variety with the compulsory licence as a basis for their breeding, have to go through the same process again and so on in perpetuity. And all of them have to pay a licence fee.
6. Negotiating a licence and especially fighting for a licence in court is often an insurmountable obstacle for most medium and small sized breeders.
7. To enforce the right to a licence the breeder using the patent must first show that *"efforts by the applicant to obtain a contractual licence on appropriate market terms within a reasonable period of time have [not] been unsuccessful.* This is time consuming and dissuasive.
8. It cannot be compared with the breeders' exemption under Plant Variety Protection law, where there is no need to negotiate and no need to pay.
9. Only breeders using the patented "invention" to develop a new variety have the right to a licence. There is no way for farmers who just want to plant the variety to have a licence.
10. And lastly, but most importantly: Such a solution does not question the legitimacy of patents on products derived from essentially biological processes. It does not answer the request in the European Parliament resolution asking for *legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes.*
11. The demand made by the European Parliament and also by many breeders' organisations, farmers' organisations and civil society groups, is to exclude from patentability conventionally bred plants – it is not a call to allow easier licencing of such patents. Simply working on an amendment or a new interpretation of the criteria for compulsory licences is not an adequate response in dealing with the question of patentability.
12. It has often been argued that the Biotech Directive should not be re-opened. But in order to have a clear legal basis for the integration of the Swiss proposal in EU law, the Biotech Directive would most likely need to be changed. In Switzerland, the aforementioned clarification has been integrated into the patent law.

3. Further aspects in regard to future development of European patent law

In discussions on the future of European patent law, some experts are proposing the introduction of a compulsory licence system for plant breeders that would make it clear that all varieties entered in the official seed catalogue have the right to receive a licence under patent law.[40]

Compared to Swiss patent law, this would in theory facilitate the application of the compulsory licence. However, this approach will not solve any of the problems since, for example:

- The scope and terms of the licence would still be limited to the purpose for which it has been granted, creating uncertainties for further downstream breeding and usages. For example, breeders who want to carry out further breeding might, besides being confronted by legal uncertainties about whom to ask for licences, find themselves in a precarious situation with several patent holders and facing multiple costs for licence fees.
- The licence is likely to be restricted to a specific region. This can cause major problems for breeders serving larger markets or companies and exporting viable kernels for further usages.
- The interests of those stakeholders who not apply for the registration of a variety are still left aside. This is especially a problem for farmers in France and Spain, who have a tradition in developing and maintaining regional seeds.
- The same problem is relevant for all animal breeders. They are affected by patents to same extent as plant breeders, but are unable to register races. Consequently, they will also be unable to obtain a licence.

From a broader perspective, the application of patents in the conventional breeding of plants and animals is not beneficial to innovation in breeding. At the same time, it is difficult to mitigate the negative consequences by, for example, introducing full breeders' exemption or an automatic licensing system into the patent system. These approaches would require changes in EU regulations and national laws, but would not provide the legal certainty that plant and animal breeders need.

It is obvious that the introduction of a new compulsory licence system would benefit patent lawyers, patent holders and to some extent also the European Patent Office. They all gain financially from granting, challenging and licensing patents. Additionally, breeders and downstream markets would be burdened by higher costs. These higher costs will only add to the legal uncertainties as described. In summary, these developments will substantially and negatively impact plant and animal breeding in Europe. In comparison, the solution as proposed by the EU Parliament in its resolution from 2012 [41] and the approach as taken by several Member States of the EU is much more credible in moving forward to solve the real problems: Prohibiting patents on processes and products used and produced by conventional breeders does not create any costs, does not require a change of law, covers plant and animal breeding and provides much more legal certainty.

40 See Axel Metzger, Humboldt-University Berlin, http://metzger.rewi.hu-berlin.de/aktuelles/conference/

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