NO PATENTS ON SEEDS!

Patents filed by KWS are a threat to plant breeding in Europe

KWS is filing increasing numbers of patents on conventionally-bred plants and plant genes

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Content

Summary

KWS (Kleinwanzlebener Saatzucht) has filed more than 100 international patent applications, many of which extend into conventional plant breeding. This number has risen significantly in recent years. KWS is claiming genes and gene variants that they have discovered, all of which may occur naturally or result from random mutagenesis. They claim all usages of the gene variants (screening, selecting, breeding, new or old GE techniques) as well as all plants produced using these methods that have the gene variant in their genome, regardless of whether the plants are genetically engineered or not. The claimed breeding characteristics also extend to important traits such as resistance to plant pathogens, viruses, fungal diseases, pest organisms, e.g. nematodes, or tolerance to extreme climate conditions.

Even though KWS varieties intended for sale in Europe are not produced using genetic engineering methods, the company is still attempting to use patent claims to cover the seeds it sells, and thus block free plant breeding that is guaranteed under the plant variety protection (PVP) law. At present, conventional plant breeders can use all varieties on the market to breed and sell improved varieties. This is allowed and intended under the 'breeders' exemption' in PVP law. It is a legally guaranteed freedom to operate that allows a wide range of new plant varieties to be generated.

However, any breeder using the KWS patented varieties to breed and market, e.g. improved beet or maize varieties, will need a license from KWS or possibly face lengthy and expensive patent litigation. As a result, access to biological diversity, which all breeders need for further breeding, can be restricted, hindered or even blocked by such patents.

Developments such as these can lead to a 'lockdown' in conventional breeding, as the uncertainties in regard to the scope of the patents and any legal implications are difficult for traditional breeding companies to navigate. It is a huge deterrent to conventional breeders if, in future, they have to fear that their new varieties might fall under the scope of patents held by large corporations.

KWS should in their own interest withdraw these patents or strictly limit them to genetic engineering methods. Rather than extending patent law into areas for which it was never intended, KWS should instead reflect upon its responsibility towards the future of plant breeding and actively support prohibitions in patent law - thus fulfilling its obligations to agriculture and food production.

Introduction

Kleinwanzlebener Saatzucht (KWS) is one of the ten biggest seed companies in the world. Unlike other big companies, such as Bayer (formerly Monsanto), Corteva (formerly DowDuPont), Syngenta / Chemchina and BASF, KWS has a tradition based in plant breeding and not in agrochemicals. Compared to the three biggest seed companies its market share is, however, much smaller.[1]

Table 1: Biggest international seed companies (Source: ETC Group, 2020)

Leading Companies by Seeds & Trait Sales, 2020

Ranking	Company /Headquarters	Seeds & Trait Sales $US millions	% Global Market Share
1.	Bayer[13] (Germany)	10,286	23
2.	Corteva Agriscience[14] (USA)	7,756	17
3.	ChemChina/ Syngenta[15] (China)	3,193	7
4.	BASF[16] (Germany)	1,705	4
5.	Groupe Limagrain/ Vilmorin & Cie[17] (France)	1,684	4
6.	KWS[18] (Germany)	1,494	3
	TOTAL TOP 6	**26,118**	**58**
7.	DLF Seeds[19] (Denmark)	1,153	3
8.	Sakata Seeds[20] (Japan)	648	1.0
9.	Kaneko Seeds[21] (Japan)	570	1.0
	Total World Market	**45,000**	**100**

Source: ETC Group

KWS has traditionally focused on breeding sugar beet, but also breeds maize, other fodder plants, cereals and potatoes. It has also played an active role in the vegetable market for some years now. About 30 years ago, it was among the first to test transgenic plants, albeit without much success (sugar beet with a resistance to a virus causing rhizomania). Currently, the company is one of the stakeholders involved in developing and applying so-called New Genomic Techniques (NGT, New GE), and is one of a number of companies actively promoting the deregulation of NGT plants in Germany and the EU. Several of these stakeholders want NGT plants to be made more or less exempt from the mandatory approval process and from risk assessment. At the same time, KWS continues to sell seeds for use in organic agriculture.

1 https://www.etcgroup.org/sites/www.etcgroup.org/files/files/food-barons-2022-full_sectors-final_16_sept.pdf

KWS patent applications

KWS has filed an increasing number of patent applications within the last few years, all claiming plants and seeds both with and without genetic engineering (GE). However, in terms of numbers of relevant patent applications, KWS still lags behind the bigger players (Figure 1).

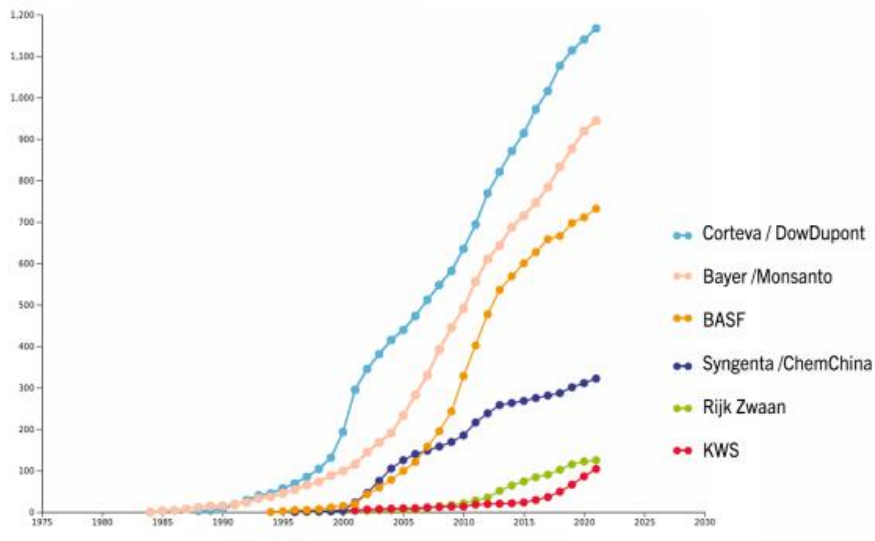

Figure 2: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82).
Source: www.kein-patent-auf-leben.de/patentdatenbank

Figure 1: Numbers of international patent applications (WIPO) for plants per company (Source: *No Patents on Life!*, 2022)

KWS has filed more than 100 patent applications through the World Intellectual Property Organisation (WIPO) in Geneva and also directly at the European Patent Office (EPO) in Munich. The filed applications claim plants and seeds as technical inventions, whereby many of them seem to focus on plants derived from Old GE (transgenic plants) or New GE. Many of these applications appear to extend to and also impact conventional plant breeding. The number of applications being filed has significantly increased within the last few years.

KWS patent applications appear to follow a specific schema: they claim genes and gene variants detected by KWS even if they may occur naturally or result from random mutagenesis. The patents claim all usages of the gene variants for breeding (screening, selecting, breeding, old and new GE), as well as all plants produced using these methods that have the gene variant in their genome, regardless of whether the plants are genetically engineered or not.

The claimed breeding characteristics include important traits such as resistance to plant pathogens, viruses, fungal diseases, pest organisms, e.g. nematodes, or tolerance to extreme climate conditions (see Table 1).

Table 2: Some recent international and European patent applications filed by KWS claiming plants, seeds and genes, with and without genetic engineering

	WO/PCT	Content	EP Status
1.	WO2017072304	Beet with inhibited bolting	EP3368677
2.	WO2017089601	Cold-tolerant plant	EP3380618, granted
3.	WO2017174406	Cereal with pathogen resistance	EP3439463
	Rule 28 (2) has to be applied for the following applications:		
4.	WO2018029300	Virus resistance to Rhizomania in beet	EP3497223
5.	WO2019038326	Fungal resistance in crop plants	EP3673051
6.	WO2019038339	Fungal resistance in crop plants	EP3673052 EP3447135
7.	WO2019206927	Digestibility in maize	EP3560330, granted EP3784030
8.	EP3696188	Resistance to fungal disease cercospora	
9.	WO2020053313	Resistance to necrotic yellow vein virus in beet	EP3849999
10.	WO2020169178	Resistance to fungal disease cercospora	EP3927724
11.	WO2020178215	Pathogen resistance in crop plants	EP3931333
12.	WO2020229533	Drought tolerance in maize	EP3969607
13.	WO2021074367	Resistance to plant diseases by downregulation of repressor genes	EP4045522
14.	WO2021058734	Repression of promotor genes	EP4034649
15.	WO2021116448	Increased cold or frost tolerance in a plant	EP4073090
16.	WO2021123396	Resistance to Northern Leaf Blight (QTL) in maize	EP4077736
17.	WO2021231467	Resistance to stalk rot in maize	not yet available
18.	WO2022013268	Resistance to Northern Leaf Blight in maize	not yet available
19.	WO2022037967	Resistance to fungal disease, cercospora, in beet and spinach	not yet available
20.	WO2022090264	Resistance to fungal disease in Brassica plants	EP3992297
21.	EP3567111	Resistance to nematodes of the genus heterodera	

The biological characteristics described in these patents can be achieved using conventional breeding and non-targeted random processes, but may be 'imitated' by genetic engineering. If these patents are granted, they are not restricted to genetic engineering, but also include conventional breeding. In fact, these patents primarily impact conventional breeders. The two case studies described below illustrate the content and the scope of the patents (patent applications).

Case study 1: Patent applications filed for sugar beet with resistance to *Cercospora beticola* (leaf spot disease)

Leaf spot disease is a fungal disease that affects beet and other crops such as spinach. KWS has filed two international patent applications for plants with increased resistance to the disease (WO2020169178 and WO2022037967 and further EP applications). It is obvious that KWS is not interested in genetically engineering the plants. For example, in regard to its beet varieties the company states that they have been made resistant to Cercospora: "*This new tolerance was found in a large breeding population that KWS derived mainly from a wide range of wild beet material.*"[2] KWS has several varieties with resistance to cercospora on offer such as: INSPIREA KWS (France), FIAMETTA KWS and BLANDINA KWS (Austria), OTTAWA KWS and BENVENUTA KWS (Italy), INSPIREA KWS and BLANDINA KWS (Germany). Further new varieties expected in 2022 are: LUDOVICA KWS, NOVATESSA KWS (Germany) and BLANDINA for organic agriculture.

The applied methods:

Both patents describe experiments using CRISPR/Cas (New Genetic Engineering) and transgenesis (Old Genetic Engineering) to generate the desired plants. However, the patents are by no means restricted to the genetic engineering techniques. Rather, the claims also extend to plants in which the desired traits have resulted from random mutations achieved by increasing the mutation rate, and also from subsequent selections and crosses. Patent WO2020169178 is based solely upon methods of genetic engineering, but patent application WO2022037967 contains a description of how the desirable gene variants were discovered in wild beet species and subsequently bred into cultivated beet varieties via selection and crossing. These examples of the processes are also typical for other patent applications listed in Table 1. It is a deliberate and systematic blurring of the technical and legal differences between genetic engineering and conventional breeding.

The claims:

The patent applications claim various gene variants that can confer specific resistances. In addition, they claim methods of identifying the plants (including via marker genes, but also phenotypically, i.e. assessing the degree of fungal attack) and also all plants carrying the corresponding gene variants in their genome. The claims extend to the use of genes discovered in varieties and in species of wild beet. Such claims are typical for other patent applications listed in Table 1. Ultimately, the claims in the patent applications are by no means restricted to specific technical processes, they also significantly restrict the rights of breeders to use existing genetic diversity for breeding new varieties.

Case study 2: Patent granted on the breeding of maize with improved digestibility

Patent (EP3560330) was granted in June 2022 to the KWS for maize with improved digestibility, regardless of whether or not the plants were bred using randomly mutated genes or produced using genetic engineering. This patent is particularly controversial because it was granted after the new Rule 28 (2) of the EPC came into force, which prohibits patents on conventionally-bred plants.

2 https://www.kws.com/de/de/beratung/saatgut/sortenwahl/sortenwahl-zuckerruebe/cr-die-neue-generation-cercospora-sorten/ (own translation)

The applied methods

Again the description in the patent includes various examples of applications with and without genetic engineering. This creates the impression that genetic engineering methods are of primary relevance in this context. However, as is also clear from the description in the patent, the relevant gene variants were discovered in certain maize plants and bred into KWS varieties using conventional breeding.

The claims

The patent claims, amongst others, plants with randomly mutated genes. The claims also cover the use of naturally occurring gene variants to select plants as part of conventional breeding. The granted claims are, therefore, clearly not restricted to genetic engineering techniques. This patent can also significantly restrict, hinder or even block the conventional breeding of plants with the desired characteristics.

Legal situation

European patent laws prohibit patents on plants derived from 'essentially biological processes' (conventional breeding). In addition, 'pure' discoveries are not patentable. However, these prohibitions are deliberately being circumvented. Both the companies and the EPO make reference to EU Directive 98/44 (Legal Protection of Biotechnological Inventions):

(1) It is in fact the case that naturally occurring wild species of beet cannot be patented. However, what the patent claims is the use of natural gene variants for further breeding or for genetic engineering processes. Companies such as KWS argue that if the genes in question are bred into other varieties, they are no longer in their natural environment and that, therefore, the wording in EU Directive 98/44 (Art 3.2) allows them to be patented. This directive allows the patenting of genes isolated from their natural environment.

(2) When the EPO grants patents such as the KWS patent on maize (EP3560330), it refers, in addition, to Art 4.2 of EU Directive 98/44 which allows patents on technical inventions in the field of plant breeding. The EU Directive does, in fact, allow patents on technical inventions in the field of plant breeding if they are not based on 'essentially biological processes'. However, these 'essentially biological processes' are not clearly defined. For example, the European Patent Office (EPO) assumes that processes for crossing and selection are not patentable, but random mutations are equated with methods of genetic engineering.

Abuse and misinterpretation of patent law:

The legal basis of the EPO is not EU Directive 98/44, but rather the European Patent Convention (EPC). Art 53(b) of the EPC, which prohibits patents on (i) plant and animal varieties and on (ii) 'essentially biological processes' for the production of plants or animals. Prior to the introduction of genetic engineering, these prohibitions were interpreted to mean that plants (and animals) were not generally patentable.[3]

This only changed when EU Directive 98/44 was adopted in 1998. Since then technical genetic inventions in plants can be patented (Art 4.2 of the Directive). If genes are isolated from their natural

3 https://www.no-patents-on-seeds.org/sites/default/files/2022-11/annex_appeal_EP2575433_%20plant%20varieties_final.pdf

surroundings, e.g. in order to transfer them across species boundaries via genetic engineering, they can (under certain circumstances) be patented Art 3.2.). However, the scope of the EU Directive is clearly restricted to genetic engineering. The prohibitions in Art 53 (b) are therefore only restricted in regard to genetically engineered plants.

Thus, according to Art 53(b), patents cannot be granted on randomly generated gene variants or conventionally-bred plants, as no technically controllable, targeted processes, i.e. genetic engineering processes, are applied in this case. Rather, conventional breeding is based on the mechanisms of evolution, which are used but not exceeded.

However, companies such as KWS, patent attorneys and also the EPO continue to reinterpret this legal situation and grant patents on processes used in plant and animal breeding even when no genetic engineering is involved at all. They also continue to 'overlook' the fact that, in accordance with EU Directive 98/44, the exemption from the prohibitions of Art 53 (b) can only be applied with regard to genetic engineering processes in which genes are isolated, transferred or altered by genetic engineering. With regard to conventional breeding, both the prohibition on the patenting of plant varieties and the prohibition on the patenting of 'essentially biological processes' must be fully respected.

The impact of the KWS patents

Even if no genetic engineering is used to generate KWS varieties used in Europe, KWS is still attempting to cover the seeds it sells with patent claims. This, however, blocks free plant breeding, which is guaranteed under the plant variety protection (PVP) law. Currently, conventional plant breeders can use all varieties on the market to breed and sell improved varieties. This is allowed and intended according to the ‘breeders’ exemption’ under PVP law. This legally guaranteed freedom to operate allows breeders to produce a wide range of new plant varieties.

However, if a breeder used the patented KWS varieties to breed and market improved beet or maize varieties, they would need a license from KWS or otherwise face possible lengthy and expensive patent litigation. As a result, access to biological diversity, which all breeders need for further breeding, is restricted, hindered or even blocked by these patents.

In the case of KWS, their aim is to control access to patented biological resources and then make as much money as possible: KWS published its own catalog in October 2022 of available plant traits, called 'native traits,' on the internet for licensing (see Table 3). Any further breeding is thus substantially restricted: if other breeders want to use the patented traits in their own varieties, they must negotiate and pay license fees.[4] The freedom to breed is being replaced with costs and contractual dependencies. It is also not clear whether licensed access will be offered for all patents. Whatever the case, privately negotiated conditions cannot be seen as equivalent to the legally guaranteed breeders’ exemption as foreseen under PVP, which guarantees freedom to operate in breeding and marketing new varieties.

4 https://www.kws.com/de/de/media-innovation/presse/press-corner/foerderung-von-innovationen-in-der-pflanzenzuechtung-kws-startet-lizenzierung-via-traitway/

Table 3: Selected examples of KWS patents (applications) and licenses on offer to other breeders (source: https://www.kws.com/corp/en/company/transparency/traitway/native-trait-catalogue/, 18 Nov. 2022)

Trait on offer for license together with the KWS patents (applications) which will probably have to be taken into account	Subject matter of the license (quoted from KWS)
Resistance to Cercospora leaf spot in sugar beet EP3696188 WO2020169178 EP3927724 WO2022037967	"*The subject matter of the license relates to seeds of Beta vulgaris ssp. vulgaris plants having a resistance against Cercospora beticola. The subject matter of the license also includes different marker-based methods for detection of Cercospora resistant Beta vulgaris ssp. vulgaris plants and respective marker.*"
Resistance to cyst nematode (Heterodera) in sugar beet EP3567111	"*The subject matter of the license relates to a method of detecting a Beta vulgaris plant being resistant against a nematode of the genus Heterodera.*"
Digestibility in maize WO2019206927 EP3560330 (granted) EP3784030	"*The subject matter of the license relates to a maize plant with improved digestibility caused by a QTL comprising a cytochrome P450 flavonoid 3`,5´-hydroxylase (F35H) gene having a mutation leading to a non-functional protein or a protein with reduced enzymatic activity. Furthermore, the subject matter of the license relates to a detection method including the usage of specific markers.*"
Resistance to Northern Leaf Blight in maize WO20211223396 EP4077736 WO2022013268	"*The subject matter of the license relates to marker-based detection methods for a maize plant having an increased resistance to Exserohilum turcicum. This increased resistance is linked to the presence of a QTL allele located on chromosome 4 (HTM) in a maize plant.*"
Cold tolerance in maize WO2017089601 EP3380618 (granted)	"*The subject matter of the license relates to a novel chill-tolerant plant as well as to the detection of such a chill-tolerant plant using specific markers for an interval on chromosome 4.*"
Fungal resistance in Brassica plants WO2022090264 EP3992297	"*The subject matter of the license relates to marker-based detection methods and respective markers for plants having Phoma stem canker resistance and reduced linkage drag.*"

Traditional plant breeding is being threatened with 'lockdown'

Patents create monopolies. If patents are granted on conventionally-bred plants and animals, all other breeders can be excluded from using them for the production and marketing of new varieties, or become dependent on the patent holder through licensing agreements. Without patents, all breeders are able, under the rules of PVP law, to use all plant varieties to breed new, improved varieties. The current basis for innovation in plant breeding may now be blocked by an impenetrable thicket of patent applications claiming the genomes of food crops.[5] New Genetic Engineering is a major driver of this development. If patents are granted on New Genetic Engineering applications, this will, in many cases, lead to plants derived from conventional breeding falling within the scope of the patents. At the same time, the differences between conventional breeding and genetic engineering are being systematically blurred in order to more easily enforce the patent claims. This means that traditional breeders will no longer have the necessary freedom to operate and will be unable to develop and market their new varieties.

Free access to genetic resources is essential for conventional breeding: traditional breeders select plants on the basis of phenotypes and genotypes (marker-assisted selection). For this to happen, access to, and use of, respective genetic resources must be freely available. Even the scientists applying New Genetic Engineering depend on access to natural genetic diversity, e.g. to program their 'gene scissors' to find the target locations in the genome, and for the direct insertion of desired gene variants if these are detected in other varieties or species.

However, if patent claims cover plants inheriting specific gene variants in their genome, the patent holder can block, hamper and control further breeding with these plants. The same applies to patent claims covering the use of genetic variants originating from the natural gene pool of plant species.

KWS is by no means the only company filing such patent applications. Syngenta/ChemChina, for example, has filed patent applications claiming the use of thousands of gene variants (also known as 'single nucleotide polymorphisms', SNPs) of arable plants, such as soybean and maize, amongst others, which occur naturally and can, for example, strengthen plant resistance to diseases (WO2021000878, WO202103391, WO2021154632, WO2021198186, WO2021260673). In most cases, the respective gene variants were discovered in wild relatives of the bred varieties.[6]

These kind of patent applications mean that traditional breeders face considerable legal uncertainties. It may be almost impossible to find out whether a particular soybean plant with increased resistance to Asian soybean rust carries in its genome any of the approximately 5000 gene variants listed in patent application WO2021154632. If these patents are granted, breeders will no longer be able to use all varieties for further breeding. They cannot even switch to related wild species of soybean for breeding since any use of the specific genes will be covered by the patents. As a result, these patents represent an impenetrable thicket for all other breeders.

Ultimately, this can result in a 'lockdown' for conventional breeding, as the uncertainties surrounding the scope of the patents and their legal implications are very difficult for traditional

5 See also Tippe R., Moy, A-C., Eckhardt J., Meienberg F., Then C. (2022) Patents on genes and genetic variations block access to biological diversity for plant breeding: patent research conducted in 2021 shows how industry is trying to patent genes, plants, seeds and food. *No Patents on Seeds!*, https://www.no-patents-on-seeds.org/en/report2022

6 See Fn. 4

breeding companies to navigate. It is a powerful deterrent to conventional breeders if they fear that their new varieties will in future be subject to patents held by large corporations.

These legal uncertainties also increase the risk that plant breeding (also in view of the EU's "Green Deal" and "Farm to Fork" strategy) will fall far short of its potential to provide important innovations in agriculture and food production. These patents are thus jeopardizing the future of our food.

The responsibility of KWS

While KWS is publicly in favour of deregulating 'New Genetic Engineering', the company still relies primarily on conventional breeding. It is attempting to extend its patents into traditional breeding by deliberately and systematically intermixing genetic engineering and conventional breeding in its patent applications. It is a strategy based on ambiguity - driving company policy in the wrong direction and undermining plant variety protection. This will ultimately restrict, control or even block access to biodiversity.

KWS has itself in the recent past expressed deep concerns about patents on conventional breeding. This was in 2018, when the EPO decided that while patents on the processes of conventional breeding were prohibited, the resulting plants and animals could still be patented. The EPO was, therefore, considering no longer applying Rule 28 (2) of the EPC which includes the respective prohibitions. This decision was reversed in 2020.[7] At that time, in December 2018, KWS stated on their website:[8]
"*It is KWS' conviction that the EPO's decision weakens the breeder's exemption. The latter permits any breeder to use protected varieties of its competitors, even without their consent, to breed new varieties and market the resultant new varieties. The breeder's exemption is one of the reasons why such strong breeding progress has been made in Germany. It helps ensure that farmers obtain new, high-performance varieties every year. (...)*

In order to breed new varieties with better traits, breeders need starting material that has as much genetic diversity as possible. In years or even decades of work, crossing it and selection can create crops that offer higher yield, better resistance to pests or tolerance to aridity. Less biodiversity restricts that work."

KWS appears to have in the meantime at least partially changed its position. The company has been filing increasing numbers of patent applications covering conventional breeding and restricting access to biological diversity for other breeders. Nevertheless, the numbers of patents filed by the various companies (Fig. 1) show that KWS will hardly be among the winners in the race for patents. The company's market share also seems rather too small for it to survive against other competitors marketing patented seeds (see Table 1). The position taken by the company against the breeder's exemption shows that not only is it endangering its own position, it is also threatening its co-competitors in traditional breeding, whose freedoms are being increasingly restricted. There is a real danger of continuing the developments which started with transgenic plants: fewer and fewer large corporations will control ever larger shares of the seed market.

7 https://www.no-patents-on-seeds.org/en/news/G3-19
8 www.kws.com/corp/en/press-dialogue/press/kws-believes-the-epo%E2%80%99s-patent-decision-weakens-the-breeder%E2%80%99s-exemption/

The overall impact is comparable to an ‘arms race’ for patents which will lead to corporate control of nearly all genetic diversity relevant to plant breeding. Smaller companies will be forced out of the market since they do not have the legal resources to apply for patents. These developments are a major threat to the future of plant breeding and food production. PVP law, which guarantees independence for all breeders and the freedom to breed new varieties using conventional methods, is the only way out of this situation.

Against this backdrop, KWS should in its own interests withdraw its patents or limit them to genetic engineering methods. Instead of extending patent law to areas for which it was never intended, KWS should remember its responsibility to the future of plant breeding and support effective prohibitions in patent law to safeguard agriculture and food production.

The demands of *No Patents on seeds!*

1. Definition of “essentially biological processes”

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

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

It has to be made clear that all ‘products’ used in or emanating from ‘essentially biological processes’ are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information. Any usage of naturally existing genes and genetic variations within the process of conventional plant breeding has to be excluded from patent claims.

3. Limiting the scope of protection

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