Patents on genes and genetic variations block access to biological diversity for plant breeding

Research into patent applications conducted in 2021 shows how industry is trying to patent genes, plants, seeds and food

Authors: Ruth Tippe, Anne-Charlotte Moy, Johanna Eckhardt & Christoph Then

Published by *"No Patents on Seeds!"* (www.no-patents-on-seeds.org)

LOGOS and names of the organisations added as being on our website

Table of Contents

Executive Summary....1
Extended summary....4
Free the seeds! Save the future of our food!....7
The controversy about patents on plants....8
The general problem....9
A global perspective....10
Some success for *No Patents on Seeds!*....11
New legal loopholes....12
Differences between GE and Non-GE....12
Research into patent applications covering conventional breeding and published in 2021....13
Patents on plants with specific gene variations....14
Case study (1): Enza Zaden....14
Case study (2): barley & beer....15
Case study (3): The Syngenta files....15
Case study (4): Over-patenting tomatoes....16

Executive Summary

The problem:
Patents granted on genes, seeds and food represent one of the biggest risks to global food security and regional food sovereignty. Patents create monopolies: plants and animals claimed in patents cannot be used by other breeders, gardeners or farmers for further breeding without the permission of the patent holder.

Patents on plant genes can block usage of biological diversity for all kinds of breeding, all plants and all animals. Especially patents on biological resources and genetic variations can cause a patent thicket for all medium sized and smaller breeders. The breeders exemption which, under the plant variety protection system, gives free access and freedom to operate to breeders in Europe, becomes a thing of the past.

If this development is not stopped, this will become the end of plant breeding as we know it: There is no possibility for a traditional breeder to use the existing varieties or native populations for breeding without the risk to infringe a patent. In consequence, many breeders will have to stop breeding or will get dependent from bigger companies by signing license contracts with patent holders.

The consequences are not confined to breeders: In many cases, the patents also cover the use of the harvested plants for food production. As a result, a handful of large corporations will acquire far-reaching control over our daily food production. They will decide what we eat, what farmers produce, what retailers sell and how much we all have to pay for it. These developments will also have consequences for the Global South.

The ongoing controversy about European Patent Office:
In June 2017, the European Patent Office (EPO) decided that patents on conventionally bred plants and animals should no longer be granted. However, there are still legal loopholes: The EPO does not obey the profound differences between genetic engineering (patentable) and conventional breeding (not technical, not patentable). In current EPO practice, plants derived from random genetic changes are considered to be patentable inventions.

Several companies are aware of the legal loopholes and file more and more patents on genes and genetic variations. These patents also include all plants and animals and inheriting those genes, no matter if derived from native populations crossing and selection, random processes or genetic engineering.

There are already several examples showing how the legal loopholes have allowed the EPO to grant such patents, e.g. on beer and barley, tomatoes, melons and lettuce including methods of conventional breeding.

The strategy of the big companies:
As shown in the overview of patent applications provided in this report, companies, such as BASF, Bayer-Monsanto, Syngenta or KWS try to exploit the legal loopholes: These companies are among those which systematically use random mutations and screening of plants for interesting gene variations to claim them as invention. Some of the patent applications as filed in 2021 cover dozens, hundreds or even thousands of gene variations identified in cereals such as soy and maize as well as in vegetables such as tomatoes, potatoes, spinach, cucumber or fruit plants like melons. The

companies seek patent protection for all plants and animals inheriting these genes, if derived from any kind of breeding activities.

At the same time, these companies, in their patent applications, use specific wordings by mixing technical elements (genetic engineering) with standard methods of conventional breeding to give the impression of a technical invention.

If such patents are not stopped, there will be huge implications for breeders, farmers and consumers, who are all becoming more and more dependent on big companies that can control access to biological resources needed for further breeding. Therefore, political decisions have to be taken as soon as possible – otherwise the ongoing legal uncertainty will undermine our global food security.

The political demands:
No Patents on Seeds! wants to achieve 'freedom to operate' for all European breeders, gardeners and farmers involved in conventional breeding, growing and conservation of food plants and farm animals. Access to biological diversity needed for conventional breeding must not be controlled, hampered or blocked by patents. Global food security and food sovereignty must not be endangered by exclusive property claims on biological diversity needed for plant breeding.

Extended summary

The back door for patents on conventionally bred plants and animals wide open

In June 2017, the Administrative Council of the European Patent Office (EPO) decided that patents on conventionally bred plants and animals should no longer be granted: the new Rule 28(2) was introduced into the Implementing Regulations of the European Patent Convention. The decision was a victory for the interests of the public, as well as for the numerous organisations represented in the international coalition of *No Patents on Seeds!*. The decision was confirmed in 2020 in a decision taken by the Enlarged Board of Appeal, the highest legal body of the EPO (G3/19).

However, the decision did not go far enough. Specific reasons for concern: the Administrative Council based its decision on a document prepared by the previous President of the EPO (CA/56/17). The wording of this document does not differentiate between spontaneously occurring gene variants and random mutations on the one hand, and technical interventions generated through genetic engineering (including genome editing) on the other hand. Therefore, in current EPO practice, randomly occurring mutations and plants (and animals) inheriting it, are considered to be patentable inventions no matter which method or technique was used for breeding them.

This was a door opener for an increasing number of patent applications: More and more patents are filed on genes and genetic variations (mutations) as well as on all plants and animals inheriting those genes, no matter if derived from crossing and selection, random processes or genetic engineering.

Recent examples for patent applications on biological diversity:

(1) Patent applications filed by Syngenta /ChemChina cover thousands of genetic variations (called single nucleotid polymorphism, SNPs) from food plants such as soy and maize or also vegetables which occur naturally and for example can enhance the plants resistance to plant pests (WO2021000878, WO202103391, WO2021154632, WO2021198186, WO2021260673). In most cases, the relevant genetic variations were identified in wild relatives of the domesticated varieties and introduced by crossing and selection.

The company claims the usage of the described gene variants for all purposes and all plants inheriting the genetic variations, as derived from any breeding activities. Claimed are techniques of genetic engineering (including the application of the gene scissors CRISPR/Cas) as well as traditional methods for plant breeding, such as screening for the gene variations of interest and further crossing and selection and all resulting plants and their harvest.

In effect, other breeders are threatened by major legal uncertainties. It will hardly be possible to find out if soy which show improved resistance against Asian soy rust are inheriting some of the several thousands of SNPs listed in the patent. Therefore, breeders can no longer use the existing plant varieties to create new varieties. They even can not make use of the wild populations of *glycine tomentella* for breeding because all usages of the relevant genes are covered by patents. In effect, these patents are likely to become a non-permissive jungle for all other plant breeders.

(2) Another drastic example is breeding of tomatoes with resistance to a virus called Tomato Brown Rugose Fruit Virus (ToBRFV). In this case, several companies are claiming various genomic regions as identified on the chromosomes of tomatoes. For example, chromosome 11 of the tomato, is targeted by ten patent applications stemming from five companies (such as Bayer/ Seminis,

BASF/Nunhems and Rijk Zwaan), claiming similar genomic regions and also genetic combinations which some them are overlapping. All tomato plants inheriting these genetic variations, derived from any breeding activies, are claimed as invention.

Conventional breeder which aim to provide tomato varieties with resistance to the virus, in many cases, will not know about the genotype of their plants. To avoid patent infringement cases, they would have to analyse around a dozen patent applications and screen for all genetic variants described therein. They may have to ask for around a dozen of license contracts. In many case, the breeders will come to the conclusion that they can not breed any of such tomatoes without expensive patent attorneys and comprehensive laboratory analyses.

These effects, resulting in 'over-patenting', are effectively blocking the access to the biological material needed for breeding for the desired virus resistance by traditional methods. In result, legal uncertainties and the threat of expensive legal battles are likely to prevent breeders from generating the desired tomato varieties, except a few the big companies.

So far, without patents, under plant variety protection system, all breeders could freely use all biological material to produce new and better plant variety. This driver in in innovation now will come to an end with thickets of patent applications on the genome of food plants.

There are already several examples showing how the EPO is using these legal loopholes to grant patents on conventionally bred plants e.g. on beer and barley, tomatoes, melons and lettuce including methods of conventional breeding.

Legal background:

The EU Patent directive 98/44 EC is decisive in this context. This EU regulation was integrated in the Implementing Regulations of the European Patent Convention (EPC) which is binding for the decision making of the EPO.

As it can be concluded from its Recitals (1, 2, 52, 53) and Art.16, the directive is addressing the technical developments in the context of genetic engineering. There is a historical reason for it: Before the directive came into force, the EPO had been stopping the grant of patents on genetically engineered plants and animals (T356/93). This situation triggered a lot of pressure by industry which claimed genetically engineered organisms to be their inventions. Therefore, the EU directive can be seen as reaction to this situation. However, at the same time, the directive does not provide any indication that the EU wanted to allow also for patents on conventionally bred plants and animals.

There are two crucial legal provisions in the EU directive which are relevant in this context:

(1) The directive allows for patents only on technical inventions which concern plants and animals. For example, Art 4 (2), allows for patents if on invention which are "*not confined to a particular plant or animal variety*". This addresses the possibility to transfer isolated genes from one organism to another, by the techniques of genetic engineering.

At the same time, Article 4 (1) of the EU directive as well as Art 53 (b) of the EPC prohibit patents on conventional ('essentially biological') breeding of plants and animals.

Therefore, in decisions of the Enlarged Board of Appeal (G2/07 and G1/08) it is made clear that "*genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant are patentable*", while traits which are "*the result of the mixing of the genes of the plants chosen for sexual crossing*" are not a technical invention. However, the EPO, despite the decisions G2/07 and G1/08, still considers random mutations as technical inventions.

(2) Article 3 (2) of the EU directive allows for patents on "*biological material which is isolated from its natural environment or produced by means of a technical process (…) even if it previously occurred in nature.*" This article, for example, allows for patents on genes isolated from the human body (see also Art. 5 of the directive). At the same time, plant genes that are in the context of a plant cell, a plant species or a family of plant species (which can be crossed with each other), can not be considered as 'isolated from its natural environment'.

However, industry claims patents on all usages of genetic variations as identified in plants and animals as well as on all plants and animals which are derived from breeding activity and are inheriting the genes. They ignore that, in context of plant and animals there are specific provisions, such as Article 4 of the EU directive and Art 53(b), EPC) that make it necessary to restrict the scope of patents to specific technical applications.

Conclusions

Patents create monopolies: conventionally bred plants and animals claimed in patents cannot be used by other breeders, gardeners or farmers for further breeding without the permission of the patent holder. In many cases, the patents also cover the use of the harvested plants for food production.

As shown in the overview of patent applications provided in this report, several companies actively try to exploit existing legal loopholes to claim conventionally bred plants as their invention. Companies, as well as the EPO, are seeming systematically to obscure the distinction between conventional breeding and genetic engineering. All plants (or animals) with the characteristics described in the patent, are claimed as an invention, no matter if derived from genetic engineering or conventional breeding.

This strategy is a major cause of problems in regard to the scope of patents: patents granted on plants (or animals) derived from technical processes may encompass plants (or animals) sharing the same genetic characteristics obtained from conventional breeding. This means that, even though they are not deemed patentable, plants (or animals) derived from essentially biological methods for breeding may still fall under the scope of a patent.

And also those companies which are active in genetic engineering will be affected: If SNPs get patented, they can no longer be used as template to direct the cutting of gene scissors like CRISPR/Cas without seeking permissions. It is no longer only the access to the technology which is blocked by patents, but also to the genetic diversity which is needed to apply tools like CRISPR/Cas.

If this development is not stopped, continued legal uncertainties and ongoing legal challenges will disable the future of any traditional plant breeding. The consequences will also impact on the future of food and agriculture as well as on livelihoods, including many regions in the global south. These are risks that could be further intensified and escalated by ongoing climate change.

As a result, a handful of large corporations will acquire far-reaching control over our daily food production - they will decide what we eat, what farmers produce, what retailers sell and how much we all have to pay for it. These developments will also have consequences for the Global South.

In the face of ongoing food crises fostered by climate change, the war in the Ukraine, and political instabilities in many regions, we should not allow property claims on biological diversity to, in addition, hamper breeding of our food plants. This would mean to add another major danger to food security and food sovereignty.

Current practise of patenting seeds must be considered to be one of the biggest man made risks to global food security and regional food sovereignty.

Free the seeds! Save the future of our food!

In its campaign, *No Patents on Seeds!* wants to safeguard the ‘freedom to operate’ for all European breeders, gardeners and farmers involved in conventional breeding, growing and conservation of food plants and farm animals. Access to biological diversity needed for further breeding must not be controlled, hampered or blocked by patents.

In addition, the ‘freedom to operate’ is the precondition for the future of

- Diversity in the fields,
- Farmers` rights,
- Choice for consumers and
- food security as well as food sovereignty.

According to our analysis, there are three crucial areas that need to be changed to make current prohibitions of patents on conventional breeding of plant and animals effective:

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

2. Definition of ‘products’ used or derived from breeding
It has to be made clear that all ‘products’ used in or emanating from ‘essentially biological processes’ are captured by the exclusion from patentability, including all plant/animal parts, cells and genetic information.

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

The controversy about patents on plants

‘Patents on life’ claiming plants and animals as ‘inventions’ first emerged in Europe in the 1980s when companies, such as Monsanto, started to produce genetically engineered plants. Patents on plant and animal varieties are explicitly prohibited in Europe.[1] Nevertheless, the biotech industry, supported by patent attorneys and the European Patent Office (EPO), has succeeded in making patents on seeds a reality. These developments have been driven by vested interests: agrochemical companies, patent attorneys and the EPO all profit from the patent business. Meanwhile, according to official statistics, around 4000 patents on plants and 2000 patents on animals have been granted in Europe, most of which are genetically engineered.

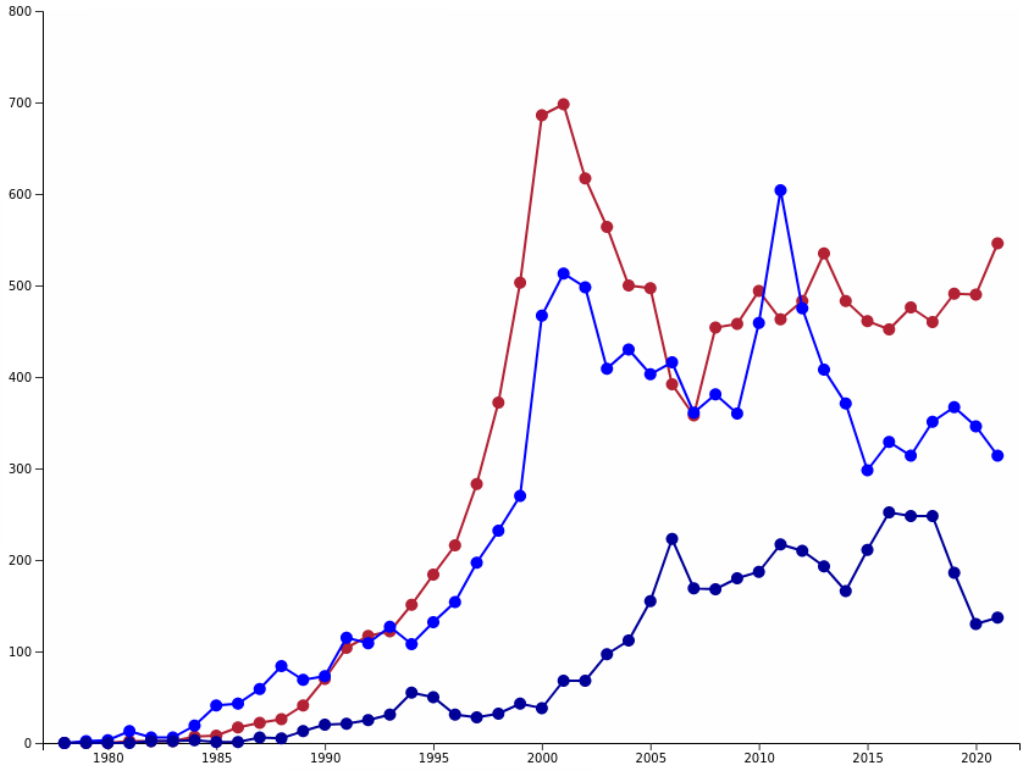


Figure 1: Patents on plants - number of patent applications for all plants under PCT/WIPO (upper line) and at the EPO (middle line) as well as patents on plants granted (lower line) by the EPO per year. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

There is an alarming trend of patents being extended to conventional breeding: within the last ten years, around 100 new patent applications involving conventional plant breeding in Europe were filed each year (via EPO or WIPO). Out of more than 1000 patent applications, more than 200 patents have already been granted, even though patents on ‘essentially biological’ (non-technical) plant and animal breeding are prohibited in European patent law (Article 53(b), EPC). Based largely on trivial technical features, such patents are frequently an abuse of patent law, i.e. they use patent law as a tool to misappropriate biological resources needed for our daily food production. *No Patents on Seeds!* specifically aims to stop these patents.

1 https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html

Every patent on conventionally derived traits can simultaneously impact the breeding of dozens or possibly more than a hundred of plant varieties.[2] Depending on the business strategy of the patent holder, licenses may be needed or access to biological resources may be blocked.

It should be noted that these patents are not just limited to plants and seeds, they also cover the harvest, and, therefore, the food (grain, fruits, drinks, vegetables and meat) that is produced. For example, in 2016, patents covering conventionally bred barley and the beer produced thereof were granted to the international companies, Carlsberg and Heineken.

The general problem

Patents create monopolies: plants and animals claimed in patents cannot be used by other breeders, gardeners or farmers for further breeding unless they have permission from the patent holder. Patents also create uncertainties: pending patent applications and ongoing legal challenges can hamper plant breeders in their freedom to operate and prevent the development of new varieties. In many cases, the patents also cover the use of the harvested plants for food production. This is entirely contrary to the current plant variety protection system (PVP), which in principle allows breeders to use the existing varieties needed for further breeding. Moreover, in regard to animal breeding, there are currently no restrictions on farmers using their livestock for further breeding or selling offspring to other breeders in Europe.

Despite the fact that patents on plant varieties are prohibited in Europe, the European patents granted on conventionally bred plants already cover several hundred varieties: as the PINTO database[3], established by European Seed Association (ESA) shows, at the end of 2020, there were 103 granted European patents listed in the database, but the number of varieties affected by these patents was more than 850 (see also Table 1). It is likely that in addition several other patents covering conventional breeding are not listed in the database and also not made accessible via license fees.

Table 1: Overview of 10 examples of European patents already granted that affect European plant varieties derived from conventional breeding (Source: www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/)

Patent	Content	Company	Number of varieties concerned
EP2961263	Lactuca sativa with resistance to downy mildew	Bejo Zaden	121
EP2515630	Genetic markers associated with drought tolerance in maize	Syngenta	93
EP2451269	Plant resistant to a pathogen	Syngenta	56
EP1804571	Resistance to virus in Capsicum plants	Monsanto	55
EP2242850	Maize plants characterized by quantitative trait loci (QTL)	Syngenta	39
EP0921720	Aphid resistance in composites	Rijk Zwaan	38
EP1525317	Clubroot resistant brassica oleracea plants	Syngenta	37
EP2586294	Peronospora resistance in spinacia	Rijk Zwaan	27
EP2164970	F. Oxysporum resistant melons	Syngenta	23

2 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/
3 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/

EP1973397	Novel cucurbita plants	Syngenta	21

A global perspective

Corporations, such as Bayer (Monsanto), Corteva (previously DowDupont/Pioneer), BASF and Chemchina (Syngenta), will prevail if patents on plants and animals are not stopped. They already own more than 50 percent of the international seed market through acquisition of breeding companies from all over the world.[4] Moreover, they could shut down free access to biological diversity needed by other breeders if they also own patents on seeds. A similar process is happening in livestock breeding where companies, such as Genus and Hendrix Genetics, have increasing influence on the international market for breeding pigs, poultry and cattle.

As a result, a handful of big corporations will acquire far-reaching control over our daily food production - they will decide what we eat, what farmers produce, what retailers sell and how much we all have to pay for it.

The numbers of all plant patent applications per year is much higher for the agrochemical companies (such as Bayer) compared to traditional breeders. As experience shows, the dynamics within the patent regimes mostly favour the larger companies (see figures 2 and 3).

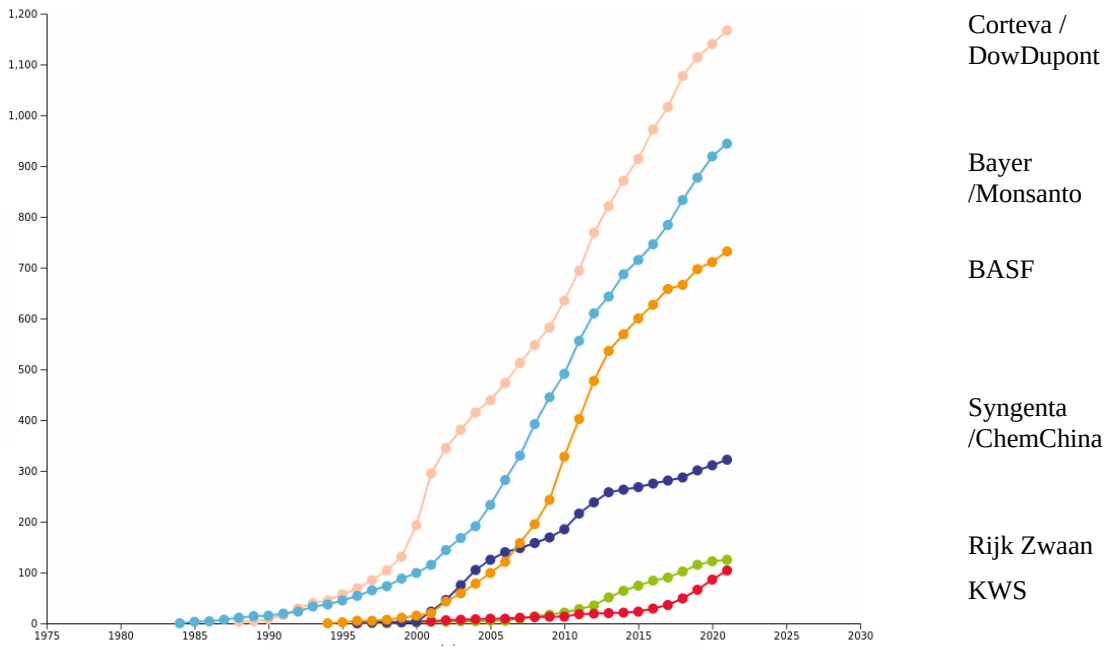


Figure 2: Patents on plants - number of patent applications for all plants under PCT/WIPO categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

4 See also: https://etcgroup.org/sites/www.etcgroup.org/files/files/etc_platetechtonics_a4_nov2019_web.pdf

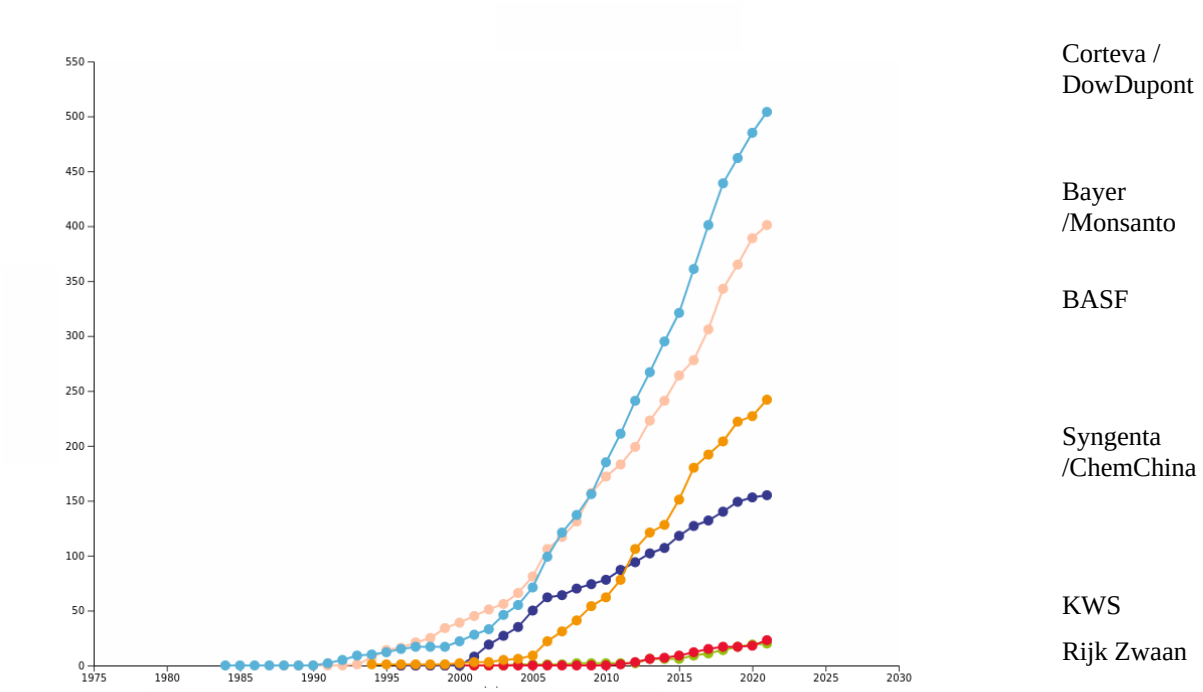


Figure 3: Patents granted on plants by the EPO, categorised by companies, per year, accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

The developments will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Previous findings[5] indicated that 75 of the 126 countries in the Global South for which data were available, are ready to allow the patenting of plants, or parts thereof. Many such patents have already been identified. This could threaten food sovereignty in these countries as well as regional traditions of production, propagation and seed exchange.

From a global perspective, agro-biodiversity is one of the most important pre-conditions for the future of breeding, as well as for environmentally-friendly agriculture and adaptability of our food production to changing conditions, e.g. climate change. In this context, patents on seeds must be seen as one of the biggest risks to global food security and regional food sovereignty.

Some success for *No Patents on Seeds!*

No Patents on Seeds! was established as a European coalition in 2007, with the aim of stopping patents from being granted on the conventional breeding of plants and animals. As the number of filed patent applications and patents granted on plants and animals derived from ‘non-technical’ but ‘conventional’ breeding grew, so did the objections. It became obvious that these patents were not

5 https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12143

based on real ‘inventions’, and, instead, represented an abuse of patent law for the misappropriation of basic resources and common goods needed for daily life. Criticism of the practice started to become more and more vocal, with support coming from civil society, farmers, breeders as well as EU institutions and national governments.

In June 2017, the Administrative Council of the EPO decided that patents on conventionally bred plants and animals should no longer be granted. This decision was based on the wording of the European Patent Convention (EPC), which prohibits patents on ‘essentially biological’ breeding (Art 53 b). The decision of the Administrative Council to change the Implementing Regulations of the EPC by adding a new Rule 28(2) was a victory for the interests of the wider public, as well as the numerous organisations represented in the international coalition of *No Patents on Seeds!*. It also reflected the demands of the EU, as set out by the EU Commission[6], the EU Parliament[7] and the Council of the EU Member States. In 2020, the decision of the Administrative Council was also confirmed by the Enlarged Board of Appeal (G3/19) which is the highest legal body of the EPO.

New legal loopholes

However, the decision did not go far enough. A specific reason for concern: the Administrative Council based its decision on a proposal made by the previous President of the EPO that still allows patents on genetic variations (‘mutations’).[8] No differentiation is made between naturally occurring gene variants and random mutations, on the one hand, and technical interventions generated by genetic engineering, including new methods such as genome editing (e.g. CRISPR/ Cas gene scissor applications), on the other hand.

This legal loophole has far reaching consequences. Companies now use specific wording in their patents to mix technical elements (such as usages of CRISPR/ Cas) with standard methods of conventional breeding: (1) Seeds, plants and harvested food derived from random processes and inheriting naturally occurring genetic variations are claimed as ‘inventions’. (2) In many cases, additional ‘technical toppings’ such as genome editing or methods of transgenesis are introduced but not necessary, to to blur the distinction between conventional breeding and genetic engineering.

Differences between GE and Non-GE

In practice, a clear distinction between the profoundly different areas of ‘biological’ processes (conventional breeding) and technical interventions (old and new methods of genetic engineering) can be easily made: conventional breeding starts from a broad range of genetic diversity, which is needed to perform further crossing and selection to derive a desired trait (breeding characteristics). Technical methods of genetic engineering involve creating plants or animals by inserting additional DNA sequences, or the direct and targeted change of specific genes in the genome, or directly generating a new trait in a given plant or animal, by for example using the gene scissors CRISPR/Cas.

6 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108(01)
7 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN and www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2015-0473&language=EN&ring=P8-RC-2015-1394
8 www.epo.org/modules/epoweb/acdocument/epoweb2/256/en/CA-56-17_en.pdf

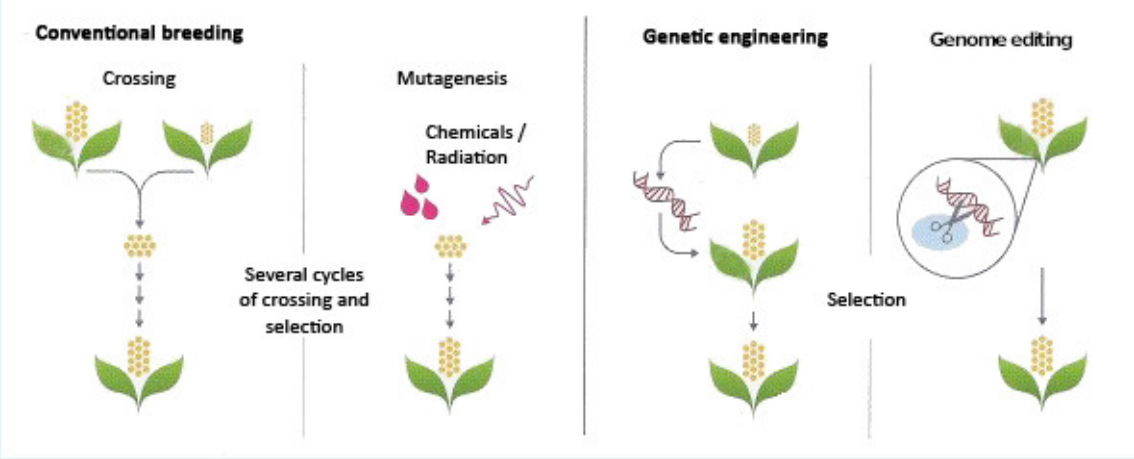


Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new characteristics into a plant.[9]

If this distinction is not established in patent law, breeders, gardeners and farmers will still be trapped by patents even if they do not use methods of genetic engineering, e.g. transgenesis or genome editing. Under these conditions, even seeds derived from conventional breeding can no longer be accessed under the conditions of PVP regime, their use will be dependent on contracts with the owner of the patents. The patent holders can hamper, restrict or block access in accordance with their own financial interests. The same problem will occur with livestock if used for breeding. Crucially, there might even be an accumulation of several patents on plants or animals after further crossing.

9 adopted from Genomxpress Scholae Nr 5, funded by the German Ministry for Education and Research (BMBF)

Research into patent applications covering conventional breeding and published in 2021

No Patents on Seeds! carried out in-depth research on international patent applications to compile a comprehensive overview of the most recent international patents filed through the Patent Cooperation Treaty (PCT) at the WIPO (World Intellectual Property Organisation). Patent applications filed at the WIPO can cover up to 100 countries where patent protection could become valid. The WIPO itself does not grant any patents, but for many companies it is a first step in filing patent applications in multiple countries around the world. Looking at recent figures, it can be estimated that two thirds of patents filed for plants at the WIPO will also become European Patent applications. On average, around one third of the European patent applications in this field will be granted (for comparison see Figure 1).

The research is based on searches of the relevant databases with specific International Classifications (IPC = A01H or C12N15/82) and names of relevant companies, as well as on the analysis of several hundred patent applications. During 2021 (and similarly as in the years before), around 300 patent applications were published for plants and plant breeding, with more than 100 applications covering conventional breeding.

Patents on plants with specific genetic variations

We found a significant number of the patent applications (around 25 % of the patent applications concerning conventional breeding) were issued on plant genes, covering up to thousands of genetic variations. The companies claim all uses of the genetic variations as well as all plants inheriting it, derived from any kind of breeding activities.

In many cases, the patent applications claim genetic variations called ‘single nucleic polymorphisms’ (SNPs). These polymorphisms, which may go along with favorable biological effects, can be found in all genes within each species. For example, SNPs can confer desired plant characteristics such as higher tolerance to plant diseases. Very often, the relevant genetic variations are found in native populations which get crossed with the commercial varieties.

The patent applications are not restricted to specific methods to generate the plants. Typical wording of the claims concern ‘plants, seeds and fruits comprising specific nucleotids’ or ‘specific nucleotids conferring desired characteristics and all plants derived from selecting and breeding comprising it’.[10]

These patent applications represent a specific strategy for circumventing the existing prohibitions under Art. 53 (b): Instead of claiming plants derived from specific techniques or methods, simply all plants are claimed which inherite the desired genetic conditions, derived from any kind of breeding activities. In summary, claimed as inventions are the genes (their variations), its usages (such as screening, breeding, genetic engineering) and all resulting plants.

Being aware of this increasing number of patent applications in this category, our research in 2021 focused on this group.

10 A similar case (WO2020239495 filed by BASF/ Nunhems) was already described in the previous report (Ref).

Table 2: Overview on examples for international patent applications on plant genes, published in 2021

Company	Number	Species	Goal
BASF/Nunhems	WO2021185774	cucumis sativus	resistance to fruit rot
	WO2021213892	tomato	resistance to ToBRF-Virus
ChemChina/ Syngenta	WO2021000878	soy	resistance to rust
	WO202103391	maize	resistance to ear rot
	WO2021154632	soy	resistance to Asian soy rust
	WO2021198186	vegetable and soy	resistance to nematodes
	WO2021260673	soy	resistance to pathogens
KWS	WO2021074367	plants	enhanced disease resistance
	WO2021093943	beta vulgaris	resistance to nematodes
	WO2021116448	beta vulgaris	cold resistance
	WO2021231467	maize	resistance to stalk root
Rijk Zwaan	WO2021110855	tomato	resistance to ToBRF-Virus
	WO2021116486	melon	resistance powdery mildew
	WO2021123429	solanaceae	resistance to torradovirus
	WO2021170850	melon / cucurbitaceae	resistance to CM-Virus
	WO2021180949	spinach	resistance to downey mildew
	WO2021255272	solanaceae / tomato	resistance to root knot nematode
	WO2021170868	tomato	resistance to ToBRF-Virus
Vilmorin	WO2021245435	melon	resistance to scab, aphids, mildew
	WO2021245282	tomato	resistance to ToBRF-Virus

Typically, the relevant genes are identified by so-called bioassays: In a first step, plants get exposed to pathogens such as fungal diseases. The plants which show natural resistance to the disease are used for gene analysis and further breeding. In most patents, the so-called ‘technical process’ is just based on the selection of the plants and their use for further crossing and selection.

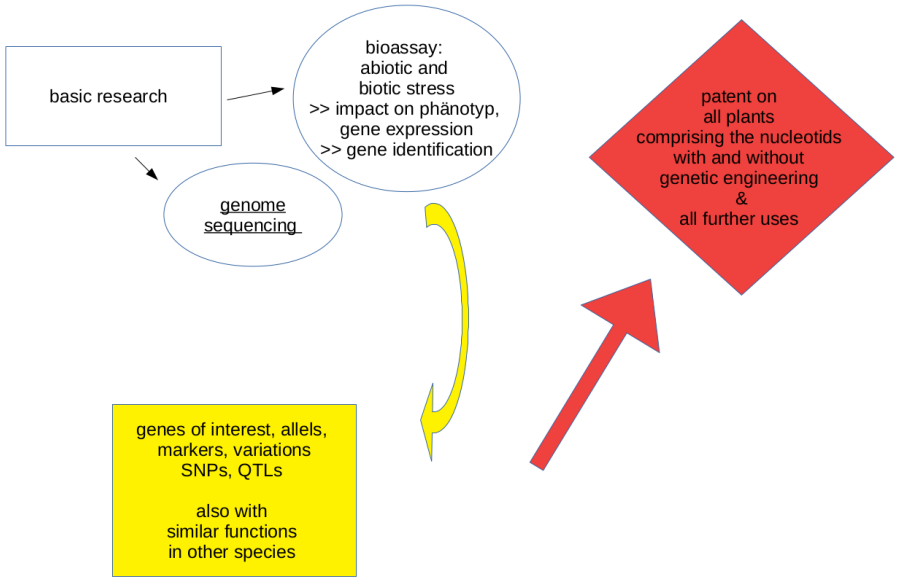


Figure 5: Overview on typical methods used in patent applications to identify genetic variations in plants with favorable biological effects, claimed as 'inventions'.

Case study (1): Enza Zaden

This patent strategy can be exemplified by patents granted for Enza Zaden in 2017 and 2018: Genes which can confer improved resistance to downy mildew (a fungal disease) were discovered in a model plant (Arabidopsis). Based on these findings, Enza filed seven patent applications on food plant species which inherit similar genetic characteristics: In result, Enza Zaden, with the help of the EPO, was able to turn one naturally occurring genetic variation into seven valid European patents:

- EP2455476, onions;
- EP2455479, tomatoes;
- EP2455480, potatoes;
- EP2455481, soy;
- EP2455474, cucumber;
- EP2455478, grape vine;
- EP 2455475, melons.

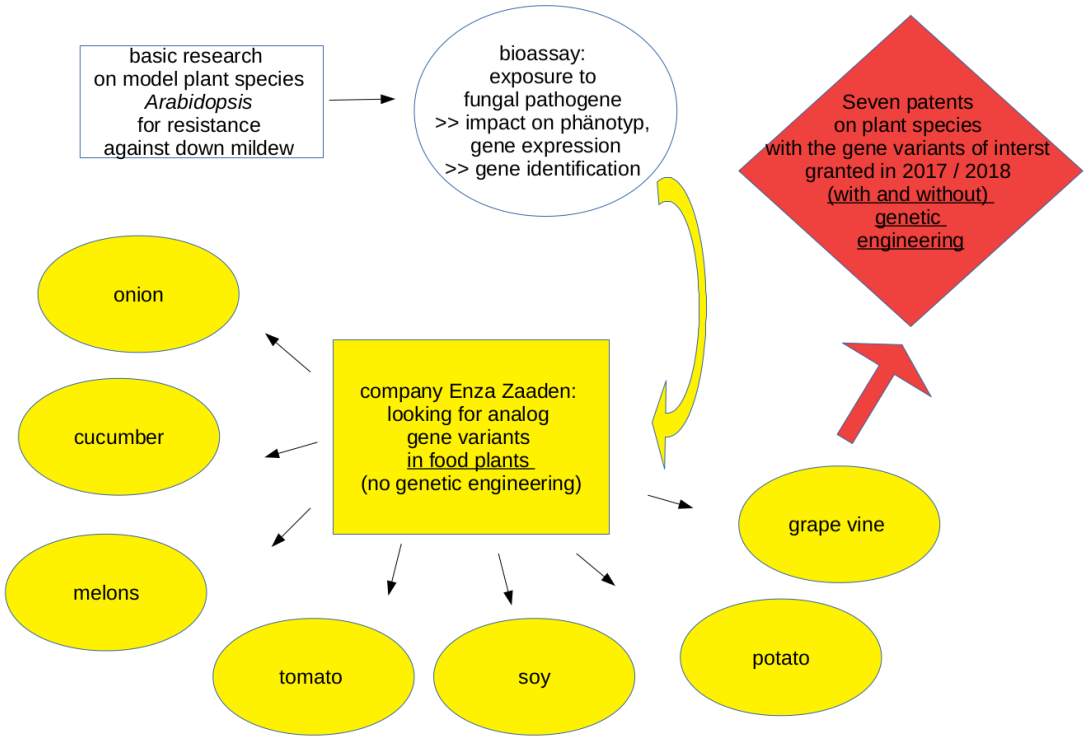


Figure 6: European patents on plants with genes which can confer improved resistance to downy mildew, granted for Enza in 2017 and 2018.

Case study (2): barley & beer

In the cases of patent applications on barley and beer, random mutations were used to generate genetic diversity which then was used for further crossing and selection. The most recent patent application of Carlsberg filed in 2021, WO2021175786, is a typical example of the way in which companies are trying to create the impression of an 'invention': the plants show random genetic variations. The claims in the patent cover all barley plants with described genetic variations, regardless of how they were achieved.

Also the use of the barley for brewing beer is claimed in patent application WO2021175786: Several types of beer are named (page 41 of the description), such as Altbier, Berliner Weisse, Blonde Ale, Dortmunder Export, Doppelbock, Hefeweizen, Helles, Kölsch, Pale ale, Pilsener, steam beer, stout, lager as well as whiskey and vodka. Producing these beverages would be subject to the patent if the specific barley is used.[11]

11 See also [report]

Table 3: Patents on barley filed by Carlsberg, based on random mutations

international application (WIPO)[12]	EP number (EPO)	Content	Legal status
WO2005087934	EP1727905	Taste of the beer; claims covering barley and beer	grant intended
	EP2290089	Taste of the beer; claims covering barley and beer	Examination
	EP2305797	Taste of the beer; claims covering barley and beer	Withdrawn 2017
WO2010063288	EP2373154	Taste of the beer; claims covering barley and beer	Granted 2016 Opposition and appeal filed, maintained
WO2010075860	EP2384110	Taste of the beer; claims covering barley and beer	Granted 2016 Opposition and appeal filed, revoked 2021
WO2011150933	EP2575433	Taste of the beer; claims covering barley and beer	Granted 2016 Opposition filed Oral hearing 10.05.2022
WO2018001884	EP 3478832	Methods for selection of barley plants (but no plants claimed as invention)	Granted 2022
WO2019129736	EP3731627	Changed quality of barley for brewing process; claims covering barley and brewing methods	Request for examination
WO2019129739	EP3731628	Changed quality of barley for brewing process; claims covering barley and brewing methods	Request for examination
WO2019134962		Changed quality of barley for brewing process; claims covering barley and brewing methods	Withdrawn
WO2021038003	EP3785529	Taste of the beer; claims covering barley plants and beer production method	Deemed to be withdrawn (09.02.2022)
WO2021069614		Methods for mutagenesis and further breeding of barley	Not yet under examination
WO2021175786		Changed quality of barley for brewing process; claims covering barley and brewing methods	Not yet under examination

12 World Intellectual Property Organisation (WIPO); many of these patents also are examined by the EPO.

Case study (3): The Syngenta files

In other cases, many genes and gene variations are claimed of specific species such as soy or maize. For example, Syngenta in its patent application WO2021154632, claims genetic variations that were detected in *glycine tomentella*, a wild relative of soy, which may confer disease resistance to Asian soy rust.

It is described that the genetic variations (single nucleotide polymorphisms, SNPs) can be introduced into soy by crossings, marker assisted selection (MAS), genome editing or gene transfer. In the patent around 5000 relevant genetic variants are listed and claimed as invention. In the examples, is shown that the genes were detected in wild populations of *glycine tomentella* which were exposed to Asian soy rust (bioassay). The relevant genetic variations then were introduced from the wild populations into domesticated varieties of soy by crossing and selection.

All soy plants which inherit the relevant genetic information are claimed as invention if they show increased resistance to Asian soy rust (ASR). Also all other usages of the gene sequences for screening and selection as well as any further breeding with the plants and genome editing are claimed as part of the invention.

In effect, other breeders are threatened by major legal uncertainties. It will hardly be possible to find out if a soy variety which shows improved resistance against Asian soy rust is inheriting some of the SNPs listed in the patent. Therefore, breeders can no longer use the existing plant varieties to create new varieties. They even can not make use of the wild populations of *glycine tomentella* for breeding because all usages of the relevant genes are covered by patents. In effect, these patents are likely to become a non-permissive jungle for all other plant breeders.

There are several similar patent applications filed by Syngenta /ChemChina in 2021 on thousands of genetic variations (SNPs) from food plants such as soy and maize or also vegetables which occur naturally and for example can enhance the plants resistance to plant pests (WO2021000878, WO202103391, WO2021154632, WO2021198186, WO2021260673).

Table 1: SNP Positions within SEQ ID NO: 1 that are associated with increased resistance to ASR

Table 1 is organized as follows: (Position in Scaffold 22052, favorable allele, unfavorable allele)

(24,A,G)(2425,G,A)(3023,T,C)(3024,C,T)(3094,A,C)(3158,A,G)(3666,G,A)(4104,C,A)(4133,T,TTGCTGCTATAATCGATTAAGC)(4155,G,C)(4156,C,A)(4157,T,C)(4159,C,G)(4160,T,G)(4239,C,A)(4289,A,G)(4321,C,T)(4355,C,T)(4474,G,T)(4528,C,T)(4659,A,C)(4820,T,C)(4906,T,G)(5028,T,G)(5077,T,C)(5202,A,C)(5228,G,A)(5254,G,A)(5291,T,C)(5316,G,A)(5613,G,A)(5649,T,C)(5744,C,T)(5755,T,TGGGTCATGGC)(5758,GACAACA,G)(6029,A,C)(6133,C,T)(6183,T,A)(6210,A,ACT)(6599,T,C)(6695,G,A)(6931,T,TG)(6937,C,T)(7007,T,C)(7030,A,G)(7094,A,G)(7117,T,TA)(7322,T,C)(7467,A,G)(7530,G,C)(7558,G,A)(8071,A,G)(8367,A,G)(8524,T,C)(8691,T,G)(8729,A,C)(8877,G,A)(8913,G,T)(9001,A,ATG)(9005,A,G)(9007,G,A)(9008,G,C)(9010,A,T)(9199,T,A)(9311,C,T)(9447,T,C)(9568,A,G)(9595,T,C)(9648,T,A)(9871,A,AC)(9896,T,A)(9911,C,T)(10105,C,T)(10319,C,T)(10443,A,G)(10487,A,C)(10497,A,G)(10567,T,C)(10738,A,C)(10914,G,T)(10945,T,A)(11114,A,C)(11134,C,A)(11155,G,T)(11219,A,G)(11272,C,T)(11869,A,G)(11975,AT,A)(12370,C,T)(12403,C,T)(12474,C,T)(12567,G,C)(12734,G,A)(12997,C,A)(13052,A,G)(13071,G,A)(13101,C,T)(13103,A,G)(13174,C,A)(13210,C,G)(13257,C,G)(13430,A,G)(13474,T,C)(13589,G,C)(13823,A,C)(13943,TA,T)(14093,A,G)(14246,C,T)(14277,G,A)(14303,A,C)(14337,G,A)(14877,T,G)(14907,T,C)(14926,A,G)(15061,C,T)(15405,A,G)(15525,A,C)(15722,T,C)(15783,C,A)(15809,A,T)(15907,ATGCATAGT,A)(15991,G,A)(16377,A,T)(16418,A,G)(16437,A,G)(16590,G,A)(16695,T,C)(16725,A,C)(16729,A,T)(16951,C,T)(17006,T,C)(17302,G,A)(17588,G,A)(17679,G,A)(18002,A,G)(18620,G,T)(18631,A,G)(18673,C,T)(19024,G,T)(19060,G,A)(19260,G,A)(19349,G,A)(19535,C,A)(19559,T,C)(19693,T,C)(19773,A,C)(19830,A,G)(20155,A,G)(20235,T,G)(20382,C,T)(2046

Figure 7: Table 1 from patent application listing the SNPs which are part of the invention: In each bracket, a favorable variant is given at a specific position in the genome which may help to increase the plant resistance to Asian soy rust. The overall number of genetic variations claimed is around 5.000 SNPs.

Case study (4): Over-patenting of tomatoes

The tomato brown rugose fruit virus (ToBRFV or TBRFV) is a plant virus that was first described in 2015 in Jordan and Israel and is spreading since then rapidly. Mostly concerned plants are tomato and peppers. It is named because of wrinkly spots (rugose) on fruits. In 2021 five patent applications on tomatoes with resistance to the pathogen were published. As further research showed, already around a dozen international patent applications on ToBRFV resistant viruses were filed by companies BASF (Nunhems), Bayer (Seminis), Enza Zaden, Philoseed, Rijk Zwaan and Vilmorin, published from 2018 till end of 2021. In most cases, the relevant genetic variations were detected in wild relatives of domesticated tomatoes.

The companies are claiming various genomic regions as identified on the chromosomes of tomatoes. For example, chromosome 11 of the tomato, is targeted by ten different patent applications stemming from five companies (such as Bayer/ Seminis, BASF/Nunhems and Rijk Zwaan), claiming similar genomic regions and also genetic combinations which some them are overlapping. All tomato plants inheriting these genetic variations, derived from any breeding activies, are claimed as invention.

This case of ‘over-patenting’, is likely to effectively block the access to the biological material needed by all breeders to generate the desired virus resistant plants: Conventional breeder which aim to provide tomato varieties and try to avoid patent infringement cases, would have to analyse around a dozen patent applications and screen for all genetic variants described therein. They may

have to ask for around a dozen of license contracts.In many cases, the breeders will come to the conclusion that they can not breed any of such tomatoes without expensive patent attorneys and comprehensive laboratory analyses. In result, legal uncertainties and the threat of expensive legal battles are likely to prevent breeders from generating the desired tomato varieties, maybe with the exception of very few the big companies.

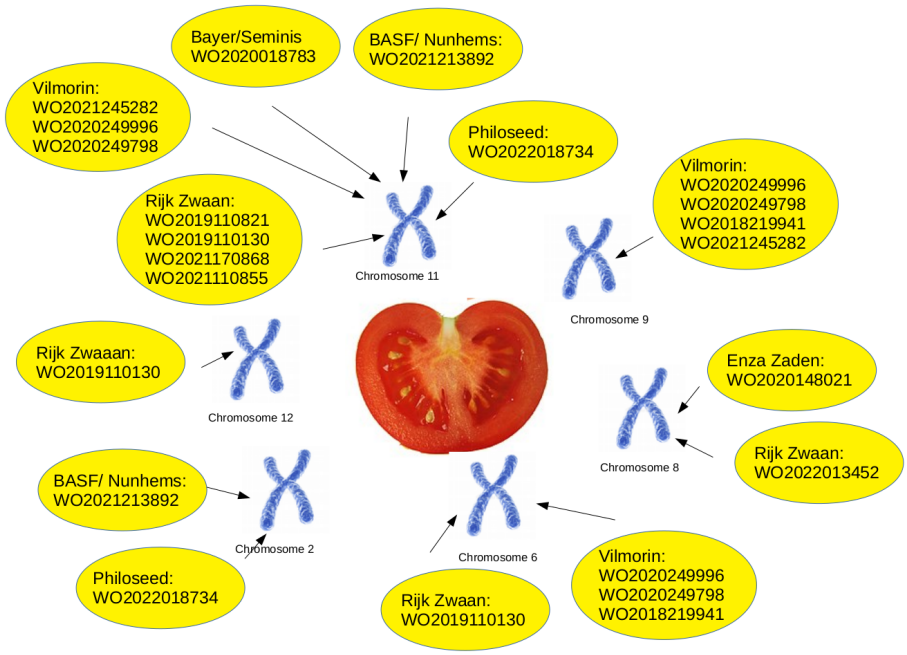


Figure 8: Patent applications from various companies on breeding of tomatoes with resistance to Tomato Brown Rugose Fruit Virus (ToBRFV). Several companies are claiming various genomic regions as identified on the chromosomes of tomatoes, which some them are overlapping. This kind of over-patenting is likely to hamper or even block the breeding of tomato varieties with the desired resistance.