

PUTTING FOOD SECURITY AT RISK: PATENTS ON CONVENTIONALLY BRED SEEDS WITH RESISTANCE TO PLANT PATHOGENS

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Summary

Research from *No Patents on Seeds!* shows that in 2024 the European Patent Office (EPO) has granted a record number of patents on classical plant breeding. More than 40 patents can be identified that concern food plants not obtained from genetic engineering processes, doubling the number from recent years. Around half of these patents are claiming plants with improved tolerance or resistance to plant pathogens such as viruses and fungal diseases.

Under the pressure of globally spreading pathogens, which can be accelerated by climate change, plant breeding has an important role to play to deliver new varieties with improved tolerance or resistance. In many cases, the gene variants needed can be found in existing biodiversity. Current examples include breeding of tomatoes to make them resistant to the Tomato Brown Rugose Fruit Virus (ToBRFV), which is a major threat to gardeners in Europe and the Middle East.

However, patents on plants with improved tolerance or resistance to plant pathogens substantially hamper or block further breeding, putting at risk the interest of the general public as well as agriculture, farmers and breeders.

Patents on plant varieties and processes for conventional breeding are prohibited in Europe, while genetically engineered plants can be patented. To undermine the prohibitions in patent law, a tendency can be observed in the patents to blur the differences between classical breeding and genetic engineering. Specifically, many patents mention the use of genetic engineering techniques, even though these were actually not necessary to produce the patented trait and it is clear from the applications that conventional breeding methods were sufficient. Such patents can be used to control access to naturally occurring biological resources. If granted, they can deter classical plant breeders from continuing their activities due to high license fees, legal uncertainties and new dependencies.

The problem is further aggravated by the introduction of new genomic techniques (NGTs) into plant breeding. NGTs can be used to 'recreate' natural occurring gene variants and to extend patent protection also to those plants that are obtained from classical breeding.

Furthermore, biotech companies can exploit genome databases and claim usage of large gene assemblies even before any plant breeding is performed. Consequently, these problems have to be solved before NGTs may be introduced into plant breeding and food production.

Freedom to operate for classical plan breeding is essential for the development of new varieties and therefore for future food security. Hence, a patent-free zone for classical breeders has to be secured.

The EU could solve the problem in the short term: Patent protection could be strictly limited to plants obtained from genetic engineering processes. This can be achieved by adopting a clarifying interpretation to the existing patent law. To tackle the problem at its root, a prohibition of patents on genetically engineered plants would require an international conference to change the substance of the European Patent Convention (EPC). Such an initiative can only be pursued in the long term.

High number of patents granted on classical plant breeding in 2024

Research shows that in 2024, the European Patent Office (EPO) has granted a record number of patents that involve conventional plant breeding of food plants. More than 40 patents were identified that concern plants that were not obtained from genetic engineering processes.

In 2020, a moratorium ended on granting of patents on conventional breeding. Since then, the number of such granted patents has now reached around 100. While between 2021-2023 below or around 20 patents were granted each year, the number of patents granted on classical plant breeding has doubled up to more than 40 in 2024. All in all, the figures from 2024 indicate an alarming trend with an increasing number of patents affecting classical plant breeders. As further research by *No Patents on Seeds!* shows, around 500 additional patent applications that concern conventional plant breeding are currently pending with up to 100 relevant new patent applications being filed each year.

Broad range of plants species and traits concerned

Concerned by several patents are lettuce, watermelon, tomatoes, honey melon, brassica oleraceae (such as broccoli, cabbage, cauliflower), cucumber, canola, spinach and pepper. Further patents are affecting breeding of bananas, maize and wheat.

Claimed are traits such as change in plant compounds, altered phenotypes, prolonged shelve life and drought resistance. By far the largest group of patents are claiming improved tolerance or resistance to plant pathogens such as viruses and fungal diseases. These patents, which account for around half of all patents granted on conventionally bred plants, are explored in more detail below.

Companies with more than one patent granted in 2024 include BASF/Nunhems, Bayer/Seminis, Bejo Zaden, ChemChina/Syngenta, Enza Zaden, Rijk Zwaan and Vilmorin.

Patents granted on naturally occurring resistance to plant pathogens

By far the largest group of patents are claiming improved tolerance or resistance to plant pathogens such as viruses and fungal diseases, some of it also bacteria or plant parasites. An overview of these patents and the species and pathogens involved is presented in <u>Table 1</u> below.

These patents entail specific problems and risks for food security: They concern plant genetic resources that are present in the current natural biodiversity, public gene banks and the breeder's gene pools. While the original plants may not be patentable, all further usages of the respective gene variants, including plant selection and breeding, the resulting plants and their seeds are subject to patent monopolies.

Thereby, access to breeding material that is needed by all plant breeders can be hampered or even blocked by the patent holder. Such patents deter other breeders from further breeding or at least substantially delay their innovation due to conditions imposed by the patent holders, high license fees or legal uncertainties. As soon as a patent application is filed, the legal status of a given biological material becomes uncertain for other breeders, leading to a deterrent effect on innovation even at this early stage. In the case of plants with resistance (or tolerance) to pathogens, this is highly problematic: In many cases, several genetic variants or plant varieties have to be combined to achieve sustained protection. Therefore, such patents are in contradiction to the need to quickly develop resistances to viruses or fungal diseases, no matter if classical methods for breeding or genetic engineering techniques are applied. Consequently, closing down access to these naturally occurring resources heavily violates the public interest.

While genetic engineering may be considered as a technical invention and subjected to patents, the free access to biological resources for all breeders is essential for our future livelihood and the transition to a more sustainable food system.

Patent	Company	Plant species	Pathogens	
EP 3358943	Nunhems	Watermelon	Cucumber Vein Yellowing Virus (CVYV)	
EP 2816891	Rijk Zwaan	Lettuce	Downy mildew	
EP 3484276	Nunhems	Honey melon	Tomato Leaf Curl New Delhi Virus (ToLCNDV)	
EP 3688016	Rijk Zwaan	Spinach	Cucumber Mosaic Virus (CMV)	
EP 3560331	Nunhems	Honey melon	Melon Yellowing associated Virus (MYaV)	
EP 2934096	Rijk Zwaan	Brassica	Clubroot	
EP 3603384	Syngenta	Lettuce	Downy mildew	
EP 3126504	Rijk Zwaan	Several species	RNA viruses of the family Potyviridae	
EP 3681271	Rahan Meristem	Banana	Fusarium oxysporum Cubensis TR4	
EP 2455479	Enza Zaden	Tomato	Phytophtora infestans	
EP 3454645	Rijk Zwaan	Spinach	Downy mildew	
EP 3629711	Vilmorin	Tomato	Tomato Brown Rugose Fruit Virus (ToBRFV)	
EP 1973397	Syngenta	Cucurbita	Cucumber Mosaic Virus (CMV)	
EP 3024929	Enza Zaden	Sunflower	Downy mildew	
EP 2393349	Bejo Zaden	Brassica	Xanthomonas campestris	
EP 3735125	Rijk Zwaan	Tomato	Tomato Brown Rugose Fruit Virus (ToBRFV)	
EP 1998608	Bejo Zaden	Brassica oleracea	Mycosphaerella brassicicola	
EP 2249634	Seminis	Lettuce	Downy Mildew	
EP 3107372	Vilmorin	Watermelon	Chlorotic Stunt Virus (WmCSV) and/or Squash Leaf Curl Virus (SLCV)	
EP 2164970	Syngenta	Sweet melons	Fusarium oxysporum f.sp. melonis (FOM)	
EP 3116304	Rijk Zwaan	Lettuce	Downy mildew	
EP 3518661	Rijk Zwaan	Spinach	Downy mildew	
EP 3864957	Nunhems	Honey melon	Melon Yellowing associated Virus (MYaV)	
EP 2139311	Bejo Zaden	Brassica oleracea	Albugo candida	

 Table 1: European patents granted in 2024 that concern classical plant breeding and resistance to plant pathogens.

Case studies: patents granted on tomatoes with resistance to ToBRFV

The Tomato Brown Rugose Fruit Virus (ToBRFV or TBRFV) was first described in 2015 in Jordan and Israel, and has been spreading rapidly ever since. It mostly affects tomato and pepper plants and takes its name from the wrinkly spots (rugose) that appear on fruits. In many cases, the relevant genetic variations that confer resistance were detected in wild relatives of domesticated tomatoes (such as *S. pimpinellifolium,* originating from Peru/Chile). Existing varieties are also reported to provide those specific genetic resources.

Two patents on conventional breeding of tomatoes with resistance (tolerance) to ToBRFV were granted in 2024:

- The patent EP 3735125 of Rijk Zwaan claims breeding processes that involve the usage of natural occurring gene variants (from *S. pimpinellifolium*) for the selection of the plants.
- The patent EP 3735125 of Vilmorin claims exclusive rights on tomato plants with tolerance / resistance to ToBRFV. The plants were detected by growing conventionally bred plant varieties (breeding lines) in the region where the virus is prevalent. The respective plants were crossed and selected and propagated by selfing. In addition, methods for detection and growing these plants are claimed as invention. The patent also mentions the possibility to obtain the plants by genetic engineering processes, which are, however, not needed.

In result, the patents as granted by the EPO comprise the future usage of naturally occurring gene variants (as well as the plants inheriting these).

Around the genetic resources needed to breed plants with resistance to ToBRFV, a patent thicket has built up: the first patent applications were filed in 2017. Meanwhile, more than 20 international patent applications filed by ten different companies, e. g. BASF, Bayer, Rijk Zwaan and Syngenta, have been published. The patent applications cover dozens of gene variants. In several cases, the claims of the different companies seem to overlap in some of the targeted genetic regions.¹

Legal and technical analysis

In Europe, patents on plant varieties and essentially biological processes are prohibited by Article 53 (b) of the European Patent Convention (EPC). The rationale behind this provision in the EPC was interpreted as a general exclusion of plant varieties from patentability. An exemption from this prohibition was made by the EU patent directive 98/44/EC, which allows for patents on technical inventions, e. g. genetically engineered plants.²

More recently, the Administrative Council of the EPO, in 2017, confirmed that plants derived from essentially biological methods (such as crossing and selection) are not patentable. In consequence, a new rule for the interpretation of Article 53 (b) was adopted. The new Rule 28 (2) was intended to strengthen the prohibitions in Article 53 (b) and is applied on patents that have been filed after 1st July 2017.³

¹ See backgrounder "How patents block the breeding of tomatoes resistant to the harmful Tomato Brown Rugose Fruit Virus", <u>https://www.no-patents-on-seeds.org/en/report-tomato</u>

² For more information see report "Seed patents: A huge challenge for the European Union", <u>https://www.no-patents-on-seeds.org/en/report-2024</u>

³ Therefore, this new rule was applied in the case of EP 3688016 (spinach, Rijk Zwaan), EP 3681271 (bananas, Rahan Meristem) and EP 3735125 (tomatoes, Rijk Zwaan). Other examples for such patents are EP 3560330 (maize, KWS) and EP 3747263 (flowers, Klemm).

A comparison of patents on conventional plant breeding before and after this key date shows some improvements, while crucial problems still remain unresolved:

- Patents applied before 1st July 2017 often claim plants that are obtained from crossing and selecting and random mutagenesis. In addition, in several cases, methods for selection by using marker genes are claimed.⁴
- Patents filed after the key date do no longer claim plants derived only from a combination of crossing and selecting. But still usage of naturally occurring gene variants, as markers for selection, and plants obtained from non-targeted random mutagenesis are claimed.

In result, no matter if applied before or after 1st of July, the patents as granted still cover plants and methods to select plants that are not genetically engineered. Thus, the patents listed in <u>Table 1</u> may impact the freedom to operate for classical breeders, no matter if filed before or after the key date (see below).

The role of NGT plant patents

Many of the patents as filed and granted are mixing elements of genetic engineering with the conventional breeding process, to give the impression of technical inventions. However, in none of the examples provided in the patents above, genetic engineering processes were needed to generate the plants.

It can be assumed that the companies filing such patents aim to control all kinds of plant breeding and therefore are blurring the legal and technical differences within patent law. These observations are especially relevant in the context of new genetic engineering (or new genomic techniques, NGTs) that can be used to 'imitate' plants (such as resistance to ToBRFV). Thereby, if combined, patents and NGTs can be used to hamper or block access to plants, including those obtained from classical breeding.

This problem can be evidenced by analyses of recently filed patents. For example, in 2023 a patent application of US company INARI was published (WO2023250505) claiming the use of DNA variants that are present in all plant species and regulate gene activity. This patent is based on a combination of new genetic engineering techniques (NGTs) and artificial intelligence (AI). In this context, AI is being used to screen plant genomes in databases for small regulatory units and their functions. This genetic information is then used to train the AI to identify the most interesting gene variants for plant breeding.

The INARI patent claims all plants obtained from this method, regardless of whether they are genetically engineered or not. Indeed, WO2023250505 does not claim any defined trait or specific plant species, but rather the use of an unlimited number of DNA sequences decisive for gene regulation in all plant species. The company is thus attempting to control access to genetic information which is relevant for all breeders.

In consequence, future plant breeding and food security may become dependent on the interest of a handful of patent holders. It is therefore necessary to consider and solve these problems if NGTs are introduced into plant breeding and food production, in addition to issues like safety, labelling and coexistence.

⁴ According to research from *No Patents on Seeds!*, more than 100 patent applications filed before July 2017 are still pending.

The impact on breeders

The Pinto database, which was established by the European Seed Association (ESA), currently lists 100 relevant European patents affecting around 1.150 conventionally bred varieties from around 40 plant species.⁵

In regard to the case study above on ToBRFV resistant tomatoes, it is interesting to see that Pinto lists two other patent applications (EP4181663 and EP3720272, not yet granted) applied by Rijk Zwaan that each concern around 30 plant varieties.

The Pinto database only lists nine patents of the patents granted on classical breeding in 2024 (see <u>Table 1</u>), but these patents sum up to 111 conventionally bred varieties that are impacted by these patents (see <u>Table 2</u>).

Patent	Company	Plant species	Number of varieties
EP 3484276	Nunhems	Honey melon	1
EP 3560331	Nunhems	Honey melon	4
EP 3126504	Rijk Zwaan	Several species	4
EP 3454645	Rijk Zwaan	Spinach	20
EP 1973397	Syngenta	Cucurbita	23
EP 2393349	Bejo Zaden	Brassica	19
EP 1998608	Bejo Zaden	Brassica oleracea	10
EP 2164970	Syngenta	Sweet melons	26
EP 2139311	Bejo Zaden	Brassica oleracea	4
Total number of impacted patents			111

 Table 2: Number of varieties concerned by patents granted in 2024 (according to Pinto database)

More generally, this situation of an increasing number of patents on conventionally bred traits creates considerable legal uncertainties and impracticability for classical breeding:

- Without the consent of the patent holder, the patented processes for identification of the patented plants cannot be used to determine whether patent-protected material is present in conventionally bred varieties or not.
- In addition, it is often impossible to determine whether the respective gene variants actually result from patented processes. In some cases, they may stem from crossing and selection, in others from random mutagenesis or, in future, from NGT applications.
- In many cases there are several patents being applied on the same traits (like ToBRFV resistance), making it difficult to decide which patents could actually be infringed.

This means that in many cases complex scientific, legal and financial questions have to be clarified in advance of the actual breeding process. The associated uncertainties and problems are likely to jeopardize the very substance of small and medium-sized plant breeding. It should not be overlooked that in many cases, varieties as listed in Pinto are already covered by several patents. Furthermore, the database does not list all varieties that are impacted by patents.

⁵ <u>https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/</u>

The factual over-patenting poses a particular threat to the necessary adaptation of existing varieties to pathogens and climate change and thus to the foundations of food security. For example, organic breeders are reporting substantial patent-related problems with breeding of tomato plant varieties with resistance to the ToBRFV⁶ which is a major threat to gardeners in Europe and the Middle East.

Licensing platforms are unsuitable for solving these problems. It is neither practicable nor financially viable for small and medium-sized breeders to sign licensing agreements with a large number of patent holders, as would be necessary in many cases. In addition, breeders may aim to avoid dependencies on bigger companies and therefore refrain from breeding new varieties with patented traits.

The way forward

The current legal framework in Europe (European Patent Convention and EU Directive 98/44) only permits patents on genetically engineered plants. Plant varieties bred by other methods therefore can only be subjected to plant variety protection.

Patents on plants not obtained by genetic engineering processes were never intended by the European legislator and pose substantial hurdles to classical plant breeders. These patents put at risk the interest of the general public as well as agriculture, farmers and breeders. In order to guarantee their freedom to operate, a patent-free zone for classical breeders has to be maintained.

Therefore, patent protection of plants should be strictly limited to plants obtained from genetic engineering processes. This could be achieved by giving updated interpretation to existing patent law. The necessary clarification can be introduced via the EU patent directive 98/44 and/or directly inserted into the rules of the European Patent Convention. In contrast, the prohibition of patents on genetically engineered plants would require an international conference to change the substance of current law.⁷

Urgency is created by the looming introduction of new genomic techniques (NGTs) into plant breeding. NGTs may be used to 'imitate' natural occurring gene variants just for the purpose to control access to biological resources needed by all breeders. Furthermore, biotech companies can exploit genome databases and claim usage of huge gene assemblies even before any plant breeding is performed.

Therefore, a solution should entail

1) ensuring only genetically engineered plants can be patented, by a clarification of the EU patent Directive 98/44 and the rules for interpretation of Article 53 (b) EPC.

2) starting an initiative for a diplomatic conference to generally prohibit patents on plants and animals under international law by changing the European Patent Convention (EPC).

⁶ <u>https://www.euronews.com/green/2024/08/18/europes-seeds-are-being-privatised-by-patents-and-it-could-threaten-food-security</u>

⁷ For more information see report "Seed patents: A huge challenge for the European Union", <u>https://www.no-patents-on-seeds.org/en/report-2024</u>