NO PATENTS ON SEEDS!



How patents block the breeding of tomatoes resistant to the harmful Tomato Brown Rugose Fruit Virus

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1. Summary

Research carried out by *No Patents on Seeds!* shows how CRISPR/Cas technology is being used to undermine the freedom to operate for conventional tomato breeders. It was found, in particular, that patents are having a detrimental effect on conventional breeding efforts to produce tomatoes resistant to the Tomato Brown Rugose Fruit Virus. The plant pathogen was first described in 2015 in Jordan and Israel and it 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 the fruits.

Many naturally occurring gene variants which may confer a high degree of tolerance or even resistance to the virus have been found. Therefore, there is no need for genetic engineering, as new varieties with the desired trait can be obtained from conventional breeding methods.

However, an already extensive 'patent thicket' has built up around the genetic resources needed for plant breeding: the first patent applications on tomato plants resistant to Tomato Brown Rugose Fruit Virus were filed in 2018 and 2019. Meanwhile, at the end of 2023, more than 20 international patent applications had been filed by ten different companies, e. g. BASF, Bayer, Rijk Zwaan and Syngenta. These patent applications also cover dozens of naturally occurring gene variants.

The companies appear to be systematically blurring distinctions between technical inventions and random processes in their patent applications. If granted, the patent holders could therefore control access to plants, regardless of whether genetic engineering is used or not. In effect, this takes away the freedom to operate for conventional breeders, as they may infringe patent rights even if they use conventional varieties as a starting point.

These patents also have detrimental effects on European plant breeders even before they are granted, as they lead to legal uncertainty, and thus act as a deterrent to the production of new varieties: conventional breeders trying to produce improved tomato varieties and, at the same time, avoid any patent infringement, would have to analyze around two dozen patent applications and screen for all genetic variations described in the various patents. As an alternative, breeders may try to take out licenses with several companies. However, both these options are substantially problematic for conventional breeders and likely to extensively block future plant breeding.

The EU needs to clarify whether only genetically modified plants can be patented, but not conventionally-bred plants. There is already a precedent: the legislator in Austria has amended national patent law and limited patents on genetically engineered seeds. According to the Austrian Patent Act, patents are not permitted if they are "*based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic modifications occurring in nature.*"
Furthermore, the effect of patents "*does not extend to plants or animals with the same specified properties which are produced independently of the patented biological material and by essentially biological processes*".

The EU now has a chance to adopt similar wording in Patent Directive 98/44 (Art. 2.2 and / or Art. 4.1), and thus put an end to the abuse of patent law. This would stop big companies from taking control of the genetic resources needed for our future food production.

2. Background

The Tomato Brown Rugose Fruit Virus (ToBRFV or TBRFV) is a plant virus that was first described in 2015 in Jordan and Israel, it 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.

Conventional breeding can provide solutions, as many gene variants that may confer a high degree of tolerance or even resistance to the virus have already been found. In many cases, the relevant genetic variations were detected in wild relatives (such as *S. pimpinellifolium*, originating from Peru/Chile) of domesticated tomatoes. Existing varieties are also reported to provide interesting genetic resources. There is no need for genetic engineering: the new varieties can be obtained from conventional breeding methods.

So far, European breeders have free access to all conventionally-bred varieties or native plants to produce new varieties. This is known as the breeders' privilege and is guaranteed by the plant variety protection (PVP) system, which is designed to provide freedom to operate. Article 53 (b) was introduced into the European Patent Convention (EPC) to avoid overlap between the breeders' privilege (PVP law) and patent law, and prohibits patents on plant varieties and conventional plant breeding. In Europe, the only exemption to these prohibitions is for genetically engineered plants (regardless of whether they are obtained from old or new genetic engineering techniques).

The breeders' privilege is a known driver of innovation in European plant breeding, ensuring 'open access' to biodiversity necessary to produce new varieties. However, if patents are granted on genetic resources, the access to biodiversity needed by all breeders for future plant breeding can be hampered or blocked.

3. How CRISPR/Cas gene scissors are being used to undermine the freedom of conventional plant breeders

Research carried out by *No Patents on Seeds!* shows how CRISPR/Cas technology is being used to undermine the freedom to operate for conventional tomato breeders. While there are many known gene variants in existing plants that may confer tolerance or resistance to the Tomato Brown Rugose Fruit Virus, a patent thicket has built up around these genetic resources: the first patent applications appeared in 2018 and 2019. Meanwhile, more than 20 international patent

applications filed by ten different companies, e. g. BASF, Bayer, Rijk Zwaan and Syngenta, have been published (see Table overview). 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.

The starting point for nearly all of these patent applications is the detection of gene variants in existing plants. CRISPR/Cas (new genetic engineering, NGT) is then subsequently used to 're-invent' (or imitate) these plants. NGTs are thus used as technical topping without actually being necessary. In these cases, it appears that NGTs were simply used to create the impression of a technical invention, while in reality, the plants are actually obtained from non-technical processes.

Consequently, the companies are able to claim the genetically engineered (NGT) tomatoes as well as characteristics of conventionally-bred varieties. The gene variants obtained from the technical processes and from random processes (used in conventional breeding) would thus be subject to 'monopoly' patent claims.

It appears that the companies are filing these patent applications to systematically and intentionally blur the distinction between technical inventions and random processes. This will take away the freedom to operate for conventional breeders who do not want to use genetic engineering techniques, as they may still infringe patents even if they use conventional varieties. The patent holder can control further breeding, regardless of whether genetic engineering is applied or not.

Table overview: Patent applications for resistance to Tomato Brown Rugose Fruit Virus (ToBRFV or TBRFV) claiming genetic resources (gene, plants, seeds), with and without genetic engineering (2018-2023). The relevant gene variants were found in existing plants, further examples of random mutagenesis and genetic engineering were added as technical toppings, but are not necessary.

Company	Number of patent application
Vilmorin	WO2018219941
Rijk Zwaan	WO2019110130
Rijk Zwaan	WO2019110821
Seminis	WO2020018783
Enza Zaden	WO2020148021
Vilmorin	WO2020249996
Vilmorin	WO2020249798
Rijk Zwaan	WO2021110855
National Agriculture and Food Research Organisation, Japan	WO2021161615
Rijk Zwaan	WO2021170868
BASF/Nunhems	WO2021213892
Vilmorin	WO2021245282
Rijk Zwaan	WO2022013452
Philoseed	WO2022018734
Tomatech	WO2022234584
Vilmorin	WO2022117884
Volcano Institute /State of Israel	WO2022091104
Volcano Institute /State of Israel	WO2023095144
Rijk Zwaan	WO2023135335

Company	Number of patent application
Syngenta	WO2023156569
Philoseed	WO2023144828
Syngenta / Nunhems/ Rik Zwaan / Takii	WO2023194291

Even though patents on plant varieties and conventional plant breeding are prohibited in Europe, hundreds of patents on conventionally-bred tomatoes, lettuce, broccoli, maize and barley have already been granted that impact more than 1200 conventionally-bred varieties.

As shown in the above list of patent applications, random mutagenesis is the 'Trojan Horse' being used to introduce patents on conventionally-bred varieties. Random mutations can be triggered by sunlight, radiation or chemical compounds. Genetic variations obtained from random mutagenesis have been used in plant breeding for decades without patents being filed to claim the plants. Indeed, in the meaning to European law, these non-predictable and non-targeted processes cannot be regarded as technical inventions.

Regardless of whether, e. g. specific mechanisms and devices for radiation are considered to be a technical invention, the plants obtained from such processes cannot be considered to be patentable. The reason: Art 53 (b) of the European Patent Convention (EPC) prohibits patents on plant varieties and conventional plant breeding, and exemptions can only be for genetically engineered plants.[1]

However, current European Patent Office (EPO) interpretation is implying the opposite and asserts that plants obtained from random mutagenesis are patentable inventions. Therefore, it has to be assumed that the EPO will, in fact, grant many of the patents listed in the overview.

4. Consequences

Conventional breeders seeking to produce tomato varieties and, at the same time, avoid patent infringement, would have to analyze around two dozen patent applications as well as screen for all genetic variations described in the patents. They may, as an alternative, possibly try to acquire license contracts with several companies. However, in the end, legal uncertainty and the threat of incurring high costs are likely to prevent them from breeding the desired tomato varieties.

These patents are detrimental to European plant breeders even before they are granted, as they lead to legal uncertainties, and thus have a deterrent effect on to the production of new varieties:

- the sheer number of patent applications filed for the desired trait and the various involved companies lead to a buildup of patent thickets that cannot be overcome by SME breeders wanting to produce new plant varieties with improved resistance to Tomato Brown Rugose Fruit Virus in the near future;
- the claims are not restricted to genetically engineered plants, but extend to characteristics present in conventional plants;
- one single variety may need several licenses before marketing could commence;

[1] https://www.no-patents-on-seeds.org/sites/default/files/news/Interpretation%20Art%2053%20(b)%20_NPoS_0.pdf

- it is unclear which patents will in the end be the most relevant and, therefore, which patent holder should be approached for a license;
- the costs for some of the licenses are reported to be very high for smaller breeders;
- even if no costs were to be incurred, smaller plant breeders would need contracts with patent holders, thus creating new dependencies on big corporations, such as Bayer, BASF and Syngenta.

These problems are very likely to substantially hinder future plant breeding. The license platforms proposed by industry as a solution, can not solve the problems: several license contracts would be needed to produce the desired trait in tomatoes, thus again strongly increasing dependencies on larger companies. This situation is likely to bring about the end of diversity in European plant breeding, which will cause further market concentration and hand the future of our food to a few large international agrochemical companies.
The consequences will be detrimental not only to tomato breeders, but will impact all sectors in future breeding, e. g. adaptation to climate change, sustainability and food security. Therefore, this is a major problem for the general public and the future of our food, which can and must be solved by political decision-making.

5. How the EU can stop patents on seeds

The independence of traditional breeders in Europe must be maintained. The necessary access to biological diversity, which is also necessary to meet the challenges of climate change and growing populations, must not be controlled, hindered or blocked by patents. Patents on processes based on crossing, selection, the use of natural genetic variations or random mutagenesis must be prohibited. Therefore, the EU needs to clarify that (if at all) only genetically modified plants can be patented, but conventionally-bred plants and the free use of conventionally bred plants cannot be hampered by patents on technical processes or patents on genetically engineered plants.

Resolutions passed in 2012, 2015 and 2019 in the European Parliament tried to enforce the current prohibitions in patent law regarding conventionally-bred plants varieties, and thus to stop the European Patent Office (EPO) from granting such patents.[2]

The EU tried to enforce these prohibitions in 2017 by implementing a decision of the Administrative Council of the EPO, but only with partial success. Meanwhile, around 1.200 conventionally-bred varieties are affected by patents.

Currently, there are ongoing discussions in the European Parliament about the regulation of plant reproductive material. Amendments that exclude patents on random mutagenesis are essential to stop patents on conventionally-bred plants: they close the door to the 'Trojan Horse' enabling the introduction of patents on European varieties. If adopted, the new wording could help to maintain biodiversity in the fields, innovation in plant breeding and the independence of European plant breeders in future. Therefore, it is in the interests of breeders, farmers and consumers to all take a stand.

[2] 2012: https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html?redirect;
2015: https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html?redirect;
2019: https://www.europarl.europa.eu/doceo/document/TA-9-2019-0020_EN.html.

6. Austria is leading the way: No patents on conventionally-bred seeds!

The legislator in Austria has already successfully amended national patent law and limited patents on genetically engineered seeds. According to the Austrian Patent Act, patents are not permitted if they are "*based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic modifications occurring in nature.*" Furthermore, the effect of patents *"does not extend to plants or animals with the same specified properties which are produced independently of the patented biological material and by essentially biological processes*"[3]

These legal provisions could be integrated into the EU patent directive 98/44 by using e. g. the wording as presented in the box below.

Box: Proposed wording for changes of the EU patent directive 98/44 to exclude patent on conventionally bred plants

Article 2 (2) is replaced by:
"2. A process for breeding of plants or animals is essentially biological, if it consists entirely of conventional breeding techniques such as crossing, selection, or the use of random or naturally occurring genetic variations."

Article 4 (1) is replaced by:
"1. The following shall not be patentable:
(a) plant and animal varieties,
(b) plant material and parts thereof, as well as genetic information contained therein, which have been obtained by plant material and parts thereof, as well as genetic information contained therein, which have been obtained by non-targeted mutagenesis.
(c) essentially biological processes for the production of plants or animals as well as plants or animals exclusively obtained by means of an essentially biological process and the genetic information contained therein."

At article 8, paragraph 3 is inserted:
"3. By derogation to paragraphs 1 and 2, the protection conferred by a patent on biological material, or extending to the use of the biological material, possessing specific characteristics as a result of the invention, shall not extend to biological material possessing these specific characteristics when these have been obtained independently from the patented invention."

The EU now has the chance to adopt similar wording in EU Patent Directive 98/44 (Art. 2.2 or Art. 4.1), and thus put an end to the abuse of patent law and stop large corporations from taking control of the genetic resources needed for our future food production.

Further information can be found on the website of *No Patents on Seeds!*:
https://www.no-patents-on-seeds.org/en/background/publications

[3] https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100