Opposition against European Patent EP 3629711 B1

Title: TOLERANCE IN PLANTS OF SOLANUM LYCOPERSICUM TO THE TOBAMOVIRUS TOMATO BROWN RUGOSE FRUIT VIRUS (TBRFV)

Application number: 18727798.3
Patent holder: Vilmorin & Cie 75001 Paris (FR)
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Opponents:

1	DE	apfel:gut e.V.
2	DE	Bingenheimer Saatgut AG
3	DE	Bioland
4	DE	Biologischer Gartenbau Wedemeyer
5	DE	BioSaat GmbH
6	DE	Culinaris - Saatgut für Lebensmittel
7	DE	Dachverband Ökologische Pflanzenzüchtung in Deutschland e.V.
8	NL	De Bolster B.U.
9	AT	Dreschflegel
10	DE	Fachgebiet Ökologische Pflanzenzüchtung und Agrobiodiversität Uni Kassel
11	DE	Florian Jordan Oldendorfer Saatzucht
12	AT	Gelawi Jaklhof
13	AT	Hintermanngütl
14	DE	Kornzept GbR
15	DE	Kulturpflanzenentwicklung Obergrashof e.V.
16	DE	Kultursaat e.V.
17	DE	Lebende Samen e.V.
18	AT	Lerchenhof
19	PT	Living Seeds / Sementes Vivas SA
20	DE	LohmannsHof Gärnterei - Inh. Max Rehberg
21	DE	Verein Keine Patente auf Saatgut! e.V.
22	NL	Prudac - Greenroad BV
23	AT	Reinsaat GmbH
24	DE	Saat:gut e.V.
25	DE	Saatzucht Projekte Kassel
26	CH	Sativa Rheingau AG
27	ES	SEAE- Sociedad española de la agricultura ecológica y agroecología
28	DE	Umweltinstitut München e.V.
29	AT	Valis Grün, Valentin Riegler, Landwirtschaft
30	AT	Verein ARCHE NOAH
31	DE	Verein zur Erhaltung der Nutzpflanzenvielfalt e.V.
32	BE	Vitale Rassen

and

Dr. Christoph Then

Frohschammerstr. 14

80807 München

(representative of the joint opposition)

Munich, 27 May 2025, Dr. Christoph Then (representing the joint opposition)

The opposition is filed against the patent as a whole. Revocation of the whole patent and, if necessary, a public hearing of the opposition is requested.

1. Overview of the reasons for the opposition under Art 100a, EPC:

1. The patent violates the prohibitions in Art. 53 (b) EPC in combination with Rule 26 (4) and Rule 27 regarding patents on plant varieties and essentially biological processes for breeding.

2. The claimed plants are not new and the patent therefore violates Art. 52 (2) and Art 54 EPC.

3. The claimed plants and processes are not inventive and the patent therefore violates Art 56, EPC.

4. The patent is a violation of Art. 53 (a) as it hampers further plant breeding needed for future food security.

2. Background:

Vilmorin claims exclusive rights to tomato plants with resistance to Tomato Brown Rugose Fruit Virus (TBRFV or ToBRFV). The plants were identified by growing conventionally-bred plant varieties (breeding lines) in the region where the virus is prevalent. The respective plants were crossed, selected and propagated via selfing.

An additional step included a genetic analysis and identification of three quantitative traits (QTLs). The QTLs were described by marker genes. However, the tomato plants with tolerance (or resistance) to TBRFV can be developed even without the inclusion of these technical elements, just by selecting the phenotype.

There are some suggestions that similar plants could also be produced using random mutagenesis or new genetic engineering methods (targeted genetic intervention using site-directed nucleases). However, these methods and techniques are simply not necessary to produce the plants, as the resistance is due to naturally occurring gene variants.

The company claims the plants (cells, propagation material, fruits) inheriting the QTLs, or at least one of the 16 marker genes. Methods of detection and cultivation are also claimed as inventions. In

essence, the claims in the patent cover the use of naturally occurring gene variants used in traditional plant breeding. Clearly, this is a massive abuse of European patent law.

The patent is a violation of Article 53 (b), which prohibits patents on plant varieties and non-technical breeding methods. It unmistakably shows that the EPO does not give proper consideration to the differences between conventional breeding and genetic engineering. This undermines and exempts the existing prohibitions in patent law, as it only allows the patenting of technical inventions.

Furthermore, the plants are neither new nor inventive.

As a result, the patent granted by the EPO undermines the future usage of naturally occurring gene variants as well as the plants and plant varieties inheriting the variants. The patent also has the potential to severely hamper or block the breeding of other tomato plant varieties with resistance to the virus, and is thus a major threat to growers in Europe and the Middle East.

The patent also creates a great deal of legal uncertainty for traditional breeders. As far as plants with resistance or tolerance to TBRFV is concerned, there is already a ‘thicket’ of patent applications that have been filed for the respective gene variants as well as detection methods.

In summary, the patent could seriously impact the activities of traditional breeders, as they could no longer use naturally occurring gene variants to produce new and improved plant varieties.

According to established EPO case law, a violation of morality (Art 53 (a) occurs when a certain kind of behaviour is considered ‘wrong’ in European culture. There is no doubt that the pursuit of profit and gain must be considered unethical ('wrong') if the harm to the public far outweighs the potential benefit.

3. The reasons for opposition:

3.1 Violation of Article 53(b)

The patent covers plants inheriting QTLs on chromosome 6 and 11, described by marker genes (Claims 1-7).

In addition, methods of detection and cultivation of the tomato plants with the QTLs (Claims 8-10) are claimed as inventions.

The plants were not produced with genetic engineering, and no genetic material was used that could be regarded as a biotechnological invention on the basis of EU Directive 98/44/EC or Rule 27, EPC. Consequently, the exemptions to the prohibitions in Article 53 (b) do not apply.

In addition, the plants claimed in the patent fulfill the criteria of plant varieties on the basis of Rule 26 (4), EPC, and cannot therefore be patented. In accordance with European law, these plants can only be protected under the plant variety protection (PVP) law.

Furthermore, Claims 8-10 are cleverly worded to escape the prohibitions in Art. 53(b). The substance of the claims is directed to nothing less than preventing other breeders from using the plant varieties (breeding lines) for further breeding with essentially biological processes. Therefore, these claims also have to be regarded as a violation of the EPC.

3.1.1 The exemptions from the prohibitions of Article 53 (b) as laid down in in EU Directive 98/44/EC and Rule 27 (EPC) cannot be applied

According to Article 53 (b) of the European Patent Convention (EPC), plant and animal varieties as well as conventional breeding are excluded from patentability. It states that: *"European patents shall not be granted in respect of: […] (b) plant or animal varieties or essentially biological processes for the production of plants or animals (...)"*. Up until 1998, this prohibition was interpreted in a way that prevented patents from being granted on plants or animals, even if they were genetically engineered (T356/93).

However, in 1998, the EU adopted Directive 98/44/EC on the legal protection of biotechnological inventions (EU patent directive). This directive allowed patents on inventions concerning plants and animals to be granted for the first time. While the prohibitions outlined in Article 53 (b) remained in force, legislators introduced an exemption to the prohibition. Article 4 (1) and (2) of the EU patent directive reads:

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

Rule 27 of the Implementing Regulation integrates Art 4.2 of the EU Patent Directive. It states:

> *"Patentable biotechnological inventions*
>
> *Biotechnological inventions shall also be patentable if they concern:*
>
> *(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;*
>
> *(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;*
>
> *(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety."*

Exemptions from the prohibitions need to be put into context in order to clarify their scope. As shown in the title of Directive 98/44/EC (Legal Protection of Biotechnological Inventions) and, e. g. the wording of Recitals 52 and 53 of the Directive, the legislator did not intend to allow the patentability of processes and products obtained from conventional breeding.

At the time when the Directive was being discussed and voted on in the EU Parliament, the European Patent Office (EPO) had already stopped granting patents on genetically engineered plants and animals in accordance with the T356/93 decision published in 1995. The subsequent adoption of Directive 98/44/EC was in part because the EU wanted to pave the way for plant-related inventions in the context of genetically engineered plants and animals (also see D1).

The G1/98 decision can be used to exemplify the purpose of these provisions in Directive 98/44/EC as well as its historical and technical background. G1/98 deals with the patentability of plant varieties. It has to be remembered that no matter whether a process for producing a plant is considered to be 'essential biological' or not, plants are non-patentable if they are considered to be plant varieties. Therefore, decision G1/98 is relevant to the opposed patent, even if Rule 28 (2) cannot be applied (see G3/19).

G1/98 came about due to decisions taken by the Technical Board of Appeal, i.e. T356/92 and T1054/19. At that time, the Technical Board came to the conclusion in both decisions that transgenic plants must be considered to be non-patentable on the basis of the prohibition in Art 53 (b) regarding plant varieties.

The reasons that the Enlarged Board of Appeal still went ahead and declared transgenic plants to be patentable in its G1/98 decision can be summarised as follows: some of the genetic material obtained from genetic engineering cannot be protected under plant variety protection (PVP) law. Therefore, and only under this condition, is it eligible for patent protection.

The background to G1/98 can be described from the position of the Community Plant Variety Office (CPVO) as given on page 13 of the decision: *"The exclusion of plant varieties from patentability would be seriously undermined if it could be circumvented simply by formulating claims sufficiently widely to avoid express reference to an individual plant variety. On the other hand, the CPVO stated that they had no difficulty with the acceptance of claims in relation to plant material not in the fixed form of a plant variety which would admit the possibility of protecting a plant variety containing a patented invention."*

Similarly, the Board argues on page 17: *"In contrast [to varieties], a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed (...). It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing and indefinitive number of individual entities defined by a part of its genotype or a property bestowed on it by that part. As described in more detail in the referring decision, the claimed transgenic plants in the application in suit are defined by certain characteristics allowing the plants to inhibit the growth of plant pathogens (…). The taxonomic category within the traditional classification of the plant kingdom to which the claimed plants belong is not specified, let alone the further characteristics necessary to assess the homogeneity and stability of varieties within a given species."*

According to the Board, a gap in intellectual property protection was identified in the context of transgenic plants (page 27): *"The inventor in the genetic engineering field would not obtain appropriate protection if he were restricted to specific varieties for two reasons: first the development of specific varieties will often not be in his field of activity and, second, he would always be limited to a few varieties even though he had provided the means for inserting the gene into all appropriate plants."*

Consequently, the exemptions from the prohibitions outlined in Article 53 (b) as laid down in G1/98 have to be interpreted in the historical and technical context of the introduction of transgenic plants. Therefore, the exemption from the prohibitions in Article 53 (b) cannot be expanded to:

- genetic material that is not isolated, not altered in a targeted way, or not made available for the direct introduction into the genome of plants by technical means;

- traits or plants that can also be protected under PVP law and that can be used for further breeding as intended by PVP law.

Therefore, the patent violates Article 53 (b), EPC.

3.1.2 Differences between non-patentable plants and technical inventions in regard to Rule 27

Article 53 (b) was introduced into the European Patent convention (EPC) to avoid overlap between PVP law and patent law. It prohibits patents on plant varieties and conventional plant breeding. There is one exemption to these prohibitions as far as genetically engineered plants are concerned. In order to correctly interpret the exemptions from the prohibitions on the patentability of plant varieties on the basis of Rule 27, the opposition division needs to identify features of the genetic engineering processes which make them distinguishable from conventional breeding. The opponents have therefore submitted Table 1, which lists crucial differences between conventional breeding (including random mutagenesis) and genetic engineering in regard to patent law.

Table 1: Differences between conventional breeding (including random mutagenesis) and genetic engineering relevant to the interpretation of Article 53 (b), EPC.

Criteria	Conventional breeding	Genetic engineering
Insertion of traits	Traits can only be established ex-post, from pre-existing genetic diversity by selection (crossing and selection).	Traits can be predicted (ex-ante) and directly inserted.
Transfer of traits	Traits (genetic information) can only be exchanged between the plants (crossing and selection) or by protoplast fusion.	Traits (genetic conditions) can be isolated and transferred or inserted via technical means.
Species borders	Traits can only be exchanged within species borders (closely related species, breeders' gene-pool).	Traits can be transferred or introduced without being limited by borders between the species.
Genetic diversity	The natural or induced genetic diversity limits the potential selection of desired genetic conditions (traits).	The traits are not limited by pre-existing genetic diversity.
Genetic background	The impact of the genetic background differs from case to case and can be influenced by further crossing and selection.	The impact of the genetic background can be reduced or silenced via technical means (such as additional promotors).

The tabled analysis above is in accordance with EPO examination guidelines stating: "*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 (see T 356/93). However, in such cases the claims must not, explicitly or implicitly, include the sexual crossing and selection process.*"[1]

Consequently, the provisions outlined in Rule 27 ('the technical feasibility of the invention is confined to a particular plant variety) only have a specific technical and legal meaning within the context of genetic engineering. This is the only case where a gap in intellectual property protection provided by the PVP law can be defined, and thus patent law may be applicable.

In conventional breeding, plant characteristics may be exchanged between unlimited varieties of the same species. However, conventional breeding is based on a combination of genetic material and traits that are embedded in the genetic background of the donor or receiving line in the same gene pool. The intention of PVP law is to promote the exchange of traits between plant varieties (breeding lines) within the breeders' gene pool. It is to this end that a full breeders' exemption was created within PVP law, which allows the use of existing plant varieties for further breeding. Consequently,

[1] https://www.epo.org/en/legal/guidelines-epc

there is no gap in intellectual property protection and no way of introducing patent protection. Therefore, Rule 27 does not apply to conventional breeding.

If Rule 27 and the provisions outlined in Article 4.2 of EU Directive 98/44/EC were applied to plants obtained from conventional breeding, the prohibition on the patenting of plant varieties would become meaningless and the PVP law dysfunctional.

3.1.2 The plants claimed and described in the patent are plant varieties (Claims 1-7)

The definition of plant varieties was set out in the EPC. Rule 26 (4) states: "*'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged.*"

In this case, the breeding process starts with traits (genetic variants) that are inherited in lines grown in the green house (such as those described in lines [0146] – [0148] in the patent description). These breeding lines are clearly plant varieties in the context of patent law. The lines were used for further crossing and selection, or simply propagated via selfing.

Nowhere in the whole process is any kind of genetic material isolated from a (largely) defined genetic background: the genotypes of the donor breeding lines and the receiving breeding lines, may differ, but there is no doubt that the desired trait is always integrated in a larger genetic background, which can be defined by several characteristics and a largely defined genotype. The genotype may be from one of the donor lines or from the receiving lines or crosses, but never something else. In addition, the reproducibility of the 'invention' is dependent on the deposition of breeding lines.

Using breeding lines as donor plants that can be crossed and selected with receiving breeding lines is the 'conditio sine qua non' for the production of the plants as described in the patent. The reproducibility of the 'invention' also depends on the deposition of the breeding line HAZTBRFVRES1 (NCIMB accession number 42758).

It is only in this case that genetic material that can be isolated and introduced into other plants via technical means, and may thus be patentable. This is not the case with the patent as granted.

The written statements to the examiners reveal that the patent holder has tried to create the impression that the QTLs could be isolated from the plant lines and transferred between plants that have no defined genotype. However, as evidenced in the statements made by the patent holder, the desired resistance is always embedded within a larger genetic background:

- In a letter dated 24 August 2020, the patent holder argues that, despite the large distances between the markers, the genetic regions are expected to be transferred 'en bloc'. Therefore, it is not necessary to determine the distance between the markers and the QTLs. The genotype of larger genetic regions on three chromosomes is meant to be transferred unchanged. However, this can only happen if the genotype is defined beyond the QTLs as such. Achieving the desired traits is dependent on a larger genomic context. (page 6 and 7)
- In a letter dated 12 October 2022, the patent holder argues that broader regions with a higher number of genes would confer a higher tolerance. Therefore, broader regions in the genome

are defined in the patents as relevant to the desired trait. Again, this shows that achieving desirable traits, depends on larger genomic regions that are not transferred alone. (page 6 and 7)

- In a letter dated 14 April 2023, the patent holder draws attention to the fact that the patented trait was found in commercially grown varieties in heterozygous form. These varieties, with the QTLs embedded in a specific genetic background, can be used for further crossing, selection or propagation via selfing to provide a homozygous combination of the trait by using other varieties. (page 5)
- In a letter dated 4 January 2024, the patent holder explains that it can be concluded from Example 2 in the patent description which Hazera breeding lines can be used to obtain the trait. It states that the specific hybrids were obtained from all the Hazera breeding lines with a well-defined genetic background. These plants can be used via selfing of the plants inheriting the genotype of the Hazera breeding lines. (page 3 and 4)

In addition, similar evidence can be derived from several passages in the patent description (emphasis added):
"[0087] According to another non-claimed aspect, the present disclosure also describes the use of a tomato plant of the invention, comprising homozygously the QTLs of the invention, as a breeding partner in a breeding program for obtaining S. lycopersicum plants having the improved phenotype of the invention. Indeed, such a breeding partner harbors homozygously in its genome the QTLs conferring the phenotype of interest. By crossing this plant with a tomato plant, especially a line, it is thus possible to transfer one, two or the three QTLs of the present invention conferring the desired phenotype, to the progeny. A plant according to the invention can thus be used as a breeding partner for introgressing QTLs conferring the desired phenotype into a S. lycopersicum plant or germplasm, preferably for transferring the QTL responsible for leaf resistance."

"[0093] A plant according to the invention, or grown from a seed as deposited under accession number NCIMB 42758, is thus particularly valuable in a marker assisted selection for obtaining commercial tomato lines and varieties, having the improved phenotype of the invention."

"[0109] Preferably, the S. lycopersicum plant [receiving plant] of step a) is an elite line, used in order to obtain a plant with commercially desired traits or desired horticultural traits."

"[0144] In this screening, a few tomatoes showed no foliar TBRFV symptoms and very little fruit symptoms. Out of these, two symptomless tomatoes and two susceptible tomatoes were chosen for the next stage."

"[0146] Hazera no. 1 (or HAZ1) is an indeterminate tomato of the loose type with regular, round and dark red fruits of about 170gr The plant has a dark green foliage and is resistant to Verticillium dahlia, Meloidogyne incognita, Tomato yellow leaf curl virus and Stemphylium solani.
[0147] Hazera no. 2 (or HAZ2) is an indeterminate tomato of the beef type with regular and intermediate flat, dark intense red fruits of about 280gr The plant is resistant to Verticillium dahlia, Fusarium oxysporum f.sp. Lycopersici 1,2, Tomato mosaic virus, Fulvia fulva, Meloidogyne incognita, Tomato spotted wilt virus.
[0148] Hazera no. 3 (or HAZ3) is an indeterminate tomato of the beef type with intermediate flat red fruits of about 270gr The plant is resistant to Tomato spotted wilt virus, Verticillium dahlia Fusarium oxysporum f.sp. Lycopersici 1,2 and Stemphylium solani."

"[0155] The tomato plants Hazera no. 1 and Hazera no. 2 were used to build an F2 bi-parental mapping population. The tomato plant Hazera no. 1 showing a resistant phenotype (fruit and foliar) to Tomato Brown Rugose Fruit virus was crossed with the susceptible plant in order to create an F1 which was used later to generate an F2 segregating population. Additional bi-parental population used for validation (foliar QTL) based on Hazera no. 3 and Hazera no. 4 was developed in the same manner (see example 6)."

The above findings must result in the revocation of the patent, as the parent plants described in the patent and used for the invention are breeding lines (or crosses of breeding lines), which must be considered to be plant varieties on the basis of Rule 26 (4) of the EPC.

3.1.3 The patent claims essentially biological methods and the use of plant varieties (breeding lines) for further breeding (Claims 8-10)

The original patent application WO2018219941 filed by the patent holder claimed the breeding processes based on crossing and selection as inventions (Claims 18-22). In the granted patent, the patent holder has tried to imply that the wording of the claims does not cover essentially biological processes by, for example, stating the following in the patent description (emphasis added):

"[0087] According to another non-claimed aspect, the present disclosure also describes the use of a tomato plant of the invention, comprising homozygously the QTLs of the invention, as a breeding partner in a breeding program for obtaining S. lycopersicum plants having the improved phenotype of the invention. Indeed, such a breeding partner harbors homozygously in its genome the QTLs conferring the phenotype of interest. By crossing this plant with a tomato plant, especially a line, it is thus possible to transfer one, two or the three QTLs of the present invention conferring the desired phenotype, to the progeny. A plant according to the invention can thus be used as a breeding partner for introgressing QTLs conferring the desired phenotype into a S. lycopersicum plant or germplasm, preferably for transferring the QTL responsible for leaf resistance."

However, a more thorough examination of the claims, shows that this statement is insufficient to escape the provisions outlined in Article 53 (b), EPC. While [0087] says that the patent does not claim crossing and selection, any other breeder would quickly find that Claims 8-10 would prevent them from performing essential biological processes, which are, according to G2 /07 and G1/08, are non-patentable. Other breeders would also be prevented from using plant varieties (breeding lines) that are non-patentable on the basis of Art 53 (b).

Taking into account the patent description for the interpretation of the claims, there is no doubt that processes of crossing and selection are the real substance of the claims, despite the different wording. Indeed, the Claims 8-10 are aimed at nothing less than preventing any other breeders from crossing, selecting and growing tomato varieties (breeding lines) with the desirable traits. Thus, despite this is excluded in Art 53 (b), the patent holder tries to claim it by clever wording in the patent.

Claim 8 states:
"A method for detecting and/or selecting S. lycopersicum plants having one QTL on chromosome 11 as found in the genome of the seeds of HAZTBRFVRES1 (NCIMB accession number 42758), said QTLs conferring an improved phenotype only when present homozygously (…)"

This claim not only includes methods of detection and selection, it also implies the crossing of plants to produce homozygous lines /varieties. Therefore, it is simply an equivalent wording for breeding processes based on crossing and selection using plant varieties (breeding lines).

Claim 9 similarly states:
"*A method for improving the yield of tomato plants in an environment infested by TBRFV or for reducing the loss on tomato production in condition of TBRFV infestation (…) comprising the initial step of identifying tomato plants tolerant to TBRFV, (…) and growing said tomato plants comprising homozygously in their genome said recessive QTL3 on chromosome 11 (...)*".

Again, this claim not only includes methods of detection and selection, but also implies that the plants can be crossed to produce homozygous lines /varieties. Therefore, it is simply an equivalent wording for breeding processes based on crossing and selection using plant varieties (breeding lines).

Claim 10 introduces a slight variation of the wording:
"*Use of a tomato plant tolerant to TBRFV for controlling TBRFV infestation of a field, tunnel or glasshouse, wherein said tomato plant comprises homozygously in its genome a recessive QTL2 on chromosome 9, (…) conferring to said plant tolerance to TBRFV (…).*"

Again, the detection / selection of the QTL in combination with crossing to achieve homozygous lines / varieties is simply an equivalent wording for breeding processes based on crossing and selection which uses plant varieties (breeding lines).

Headnotes 1 and 2 of the G1/08 and G2/07 decisions need to be taken into account in this context, as they state that:

> *"1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.*
>
> *2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants."*

Claims 8-10 attempt to circumvent these decisions just by using clever wording. It is now up to the EPO to prevent companies from using these simple strategies to circumvent the prohibitions outlined in Article 53 (b). If the claims were to be accepted, this would undermine both the prohibition on the patenting of essentially biological processes for breeding and the prohibition on patenting plant varieties.

3.1.4 Summary of grounds for opposition on the basis of Article 53 (b)
The wording of the claims and the examples provided in the patent show that the plants and their method of production or selection cannot be regarded as 'biotechnological inventions'. Therefore, the exemptions from the prohibitions outlined in Art 53 (b) cannot be applied. In addition, the plants as claimed fulfill the criteria of plant varieties of Rule 26 (4), EPC.

Furthermore, Claims 8-10 as granted are just cleverly worded to escape the prohibitions outlined in Art. 53 (b), but, in substance, these claims are directed to essentially biological processes and the usage of plant varieties (breeding lines) for further breeding.

Consequently, the patent contravenes the EPC and has to be revoked.

3.2 Grounds for opposition under Article 52 (2) and Article 54, EPC

According to the patent description, the claimed plants were already in existence. As explained in the patent description the plants were identified by screening tomato plants in a greenhouse:

"[0142] The inventors have screened their tomato breeding genetic material in a naturally infected greenhouse in the Southern part of Israel, in the Bsor region, which is the major tomato crop production area in Israel. About 443 different tomatoes were screened. Each tomato was planted in two repeats, 10 plant per repeat in different locations in the greenhouse.
[0143] Each row in the greenhouse contained 120 plants. At each row, a susceptible line control of 10 plants was planted. In order to spread the controls in the different places in the greenhouse, the controls were positioned in diagonal along the different rows in the greenhouse.
[0144] In this screening, a few tomatoes showed no foliar TBRFV symptoms and very little fruit symptoms. Out of these, two symptomless tomatoes and two susceptible tomatoes were chosen for the next stage."

In a letter to the EPO dated 14 April 2023, the patent holder confirms that some commercially grown lines already inherited the QTLs. These varieties can be used for further crossing, selection, or for self-propagation.

As it was found that the plants grown in greenhouse already exhibited the desired tolerance (or resistance), it cannot be claimed that the plants obtained from further crossings were the first to exhibit the trait. It was simply the previous absence of the TBRF virus that prevented breeders and gardeners from detecting those plants.

Therefore, the plants do not meet the criteria outlined in Art 54, EPC, as they are not new. Even if the markers were to be considered new, this would not mean that the plants are new inventions.

3.3 The plants are not an invention and therefore violate Article 56, EPC

The problem that needed to be solved with the 'invention' are tomato plants with improved tolerance or resistance to the TBRF virus. This was achieved by screening already existing plants under exposure to the virus as described by Luria et al., 2017 (D2). Thus, the problem-solution approach would only require a sufficiently broad range of genetic diversity in plant varieties (breeding lines) exposed to the virus.

The plants can subsequently be used for further crossing, selection, or self-propagation, all of which are non-technical and non-inventive processes.

In addition, gene analysis was performed (by standard methods) to identify markers that can be used to select plants. However, these tools are not necessary to produce the desired plants. These are optional 'add-ons' or 'technical toppings'. Therefore, these elements cannot be used to make the plants inventive.

Even if the markers were to be considered inventive, this would not make the plants inventive. It should also be born in mind that there is no 'technical teaching' in regard to the DNA sequences of the QTLs or their mode of action.

Consequently, the resulting plants lack inventiveness as set out in Article 56, EPC.

3.4 Grounds for opposition under Art 53 (a). EPC

Currently, European breeders should in principle have free access to all conventionally-bred varieties or native plants for use in producing and marketing new varieties. This is known as the breeders' privilege and is guaranteed by the plant variety protection (PVP) system. The PVP system is designed to provide breeders with the freedom to operate, and is known to promote innovation in European plant breeding. It also ensures 'open access' to the biodiversity necessary to produce and market new varieties. Ultimately, if patents are granted on genetic resources, then access to biodiversity needed by all breeders for future plant breeding can be hampered or blocked.

As recent report show (D3, D4 and D5), patent applications filed for plants with resistance to the TBRF virus are a major threat to the way breeders work, as they create patent thickets, legal uncertainty, technical hurdles, high licence fees and monopoly claims on the biodiversity needed by all breeders. This patent may substantially add to this problem: if, for example, another patent application is filed for the use of the QTL gene sequences (which were not known at the time the opposed patent was filed), this would result in even greater legal uncertainty, and may force the traditional breeders to acquire several licenses for the same trait. This situation has been caused by the abuse of European patent law, and will be a deterrent for most breeders wanting to produce the varieties urgently needed to prevent the virus from spreading further.

According to established EPO case law, a violation of morality occurs when a certain kind of behaviour is considered 'wrong' in European culture. In general, the pursuit of profit and gain must be considered to be unethical ('wrong') if the harm to the public far outweighs the potential benefit.

Against this backdrop, Article 53 a) is a high hurdle for the granting of such patents and after thorough examination must lead to the revocation of the patent. It is crucial that the EPO critically reviews and corrects both its own business practices and the corresponding interpretation of the law.

4. Attachments:

D1: *No Patents on Seeds!* (2023) Correct legal interpretation of Article 53(b), EPC, within the context of the EU patent directive 98/44/EC

D2: Luria N, Smith E, Reingold V, Bekelman I, Lapidot M, Levin I, et al. (2017) A New Israeli Tobamovirus Isolate Infects Tomato Plants Harboring Tm-22 Resistance Genes. PLoS ONE 12 (1): e0170429. doi:10.1371/journal.pone.0170429

D3: *No Patents on Seeds!* (2024) Seed patents: A huge challenge for the European Union Analysis of the problem, case studies and potential solutions.

D4: *No Patents on Seeds!* (2024) How patents block the breeding of tomatoes resistant to the harmful Tomato Brown Rugose Fruit Virus

D5: *No Patents on Seeds!* (2025) Putting food security at risk: Patents on conventionally bred seeds with resistance to plant pathogens

D6: Documents for opposition as signed by the opponents