Opposition against European Patent EP 3380618 B1

Title: PLANT WITH TOLERANCE OF THE COLD

Application number: 16804741.3
Patent holder: KWS SAAT SE & Co. KGaA
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Opponents:

„Keine Patente auf Saatgut!“ e.V.

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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.

München, 14.5.2023, Dr. Martha Mertens

München, 14.5.2023, Dr. Christoph Then

Reasons for opposition:

1. The patent violates the prohibitions of Art. 53(b) EPC regarding patents on plant varieties and essentially biological processes for breeding.

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

3. The claimed plants and processes are not inventive and, therefore, violate Art 56, EPC

4. The patent violates Art. 83 because it does not provide sufficient information to identify the claimed maize.

5. The patent is a violation of Art. 53 (a) because it hampers further plant breeding we need for our future food security

Background:
KWS produced the maize by using existing maize lines that were already known to have tolerance to growing conditions such as those in northern Europe. They analyzed the genome of the plants and identified so-called marker genes (gene variants) that can be used for screening and selecting the desired traits. Further crossing and selection was performed to see if the marker genes and the intended trait (cold resistance) were inherited together.

In addition, random mutagenesis was applied to see if these gene variants can also be achieved with this method (which is not surprising). Random mutagenesis was introduced ‘on top’ to create the impression that this was a technical invention. However, the outcomes of the random mutagenesis processes are largely impacted by the biological mechanisms in the cells, they are neither predictable nor targeted. Therefore, from the perspective of patent law, random mutagenesis is fundamentally different to the technical processes used in genetic engineering (genome editing).

Interestingly, tools such as CRISPR/Cas are mentioned in the patent description. However, these new genomic techniques were not applied, and they are not necessary to achieve the plants which already exist in nature. This case has some similarities with other patents and patent applications showing that CRISPR/Cas is being abused within the patent system as a tool to appropriate the genetic resources of biological diversity needed for traditional plant breeding.

Ultimately, targeted technical methods were not applied and they are also not necessary to breed maize with cold-tolerance. The patent explicitly states conventional breeding and usage of the existing biological diversity is the real source of this ‘invention’: on page 27, a short summary of the examples shows that further crossing and selection are sufficient to achieve the desired plants. It also explains that the majority of plants (86 % of the plants used as female part in hybrid breeding) in the existing breeders’ gene pool already inherit the gene variants that are responsible for cold tolerance. The patent as granted by the EPO comprises the future usage of these gene variants as well as of the maize plants inheriting the gene variants.

In summary, the patent is not only a violation of Article 53 (b) (prohibition on granting patents covering plant varieties and non-technical methods for breeding) it is also not inventive. This example shows how the EPO is intentionally ignoring the differences between conventional breeding and genetic engineering. This undermines and exempts the existing prohibitions in patent law, which only allows the patenting of technical inventions.

The example of the patent for cold-resistant maize (EP 3380618) shows that the detrimental effects of these patents can seriously impact the activities of traditional breeders, as they can no longer use the existing varieties to produce new and even better plant varieties. The impact of this patent is also relevant for organic maize breeders: KWS seeds are widely used for breeding maize varieties used in conventional and organic agriculture, it thus also likely that future breeding with several of these varieties will fall within the scope of the patent.

It may become very difficult for other breeders to resolve these legal uncertainties, as identification methods described in the patent can hardly be applied in practice. Furthermore, the patent also covers detection methods which cannot, therefore, be used without the permission of the patent holder.

1. Violation of Article 53(b)

Claim 1 reads (in essence): "A chill-tolerant maize plant or a portion thereof, comprising a first chromosomal interval (…) which comprises an endogenous chill tolerance- conferring nucleic acid, wherein the chill tolerance-conferring nucleic acid comprises a nucleic acid sequence selected from the group consisting of (…) ".

Original German version: "Kühletolerante Maispflanze oder ein Teil davon, umfassend ein erstes chromosomales Intervall (…) welches eine endogene Kühletoleranz-vermittelnde Nukleinsäure aufweist (…), wobei die Kühletoleranz-vermittelnde Nukleinsäure eine Nukleinsäuresequenz umfasst, ausgewählt aus der Gruppe bestehend aus (…)."

Claim 4 is independent from Claim 1 and reads (in essence): "A method for the selection of a chill-tolerant maize plant, comprising the steps of: i. identification of a chill-tolerant maize plant comprising a first chromosomal interval (…) which has an endogenous chill tolerance-conferring nucleic acid, comprising the steps of (…)".

Original German version: "Verfahren zur Selektion einer kühletoleranten Maispflanze umfassend die Schritte: i. Identifizieren einer kühletoleranten Maispflanze umfassend ein erstes chromosomales Intervall (…), welches eine endogene Kühletoleranz-vermittelnde Nukleinsäure aufweist, umfassend die Schritte (…)".

These claims do not cover genetically engineered plants which could be regarded as biotechnological inventions under EU Directive 98/44 or Rule 27. Consequently, the exceptions to the prohibitions in Article 53 (b) do not apply.

The opposition division, therefore, had to examine whether the patent comprises plant varieties and / or essentially biological methods for breeding. This examination shows that both provisions of Art 53 (b) were violated when the patent was granted.

1.1 The exemptions in EU Directive 98/44 and Rule 27 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 reads: *"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 (...)". Until 1998, this prohibition was interpreted in a way that prevented patents on plants or animals from being granted, even if they were genetically engineered (T356/93).

However, in 1998, the EU adopted the Directive 98/44 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 in Article 53 (b) are still included, an exemption to the prohibition was introduced. 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 the title of the Directive 98/44 (Legal Protection of Biotechnological Inventions) and, e. g. the wording of Recitals 52 and 53 of the Directive, show 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. This decision was harshly criticized by industry at the time. The subsequent adoption of Directive 98/44 was in part because the EU still wanted to pave the way for plant-related inventions in the context of genetically engineered plants and animals (also see Annex).

The adoption of the EU Directive did indeed lead to a significant shift in current practice at that time. It was only after the Directive was adopted and became an integral part of the new Implementing Regulations of the EPC in 1999 that further patents on plants and animals derived from genetic engineering were granted.

On the other hand, it may be concluded all processes in conventional breeding as well as all products (plants, animals, plant varieties, their characteristics, their genetic components, seeds, breeding material) are still fully excluded from patentability under Art 53 (b).

1.2 The plants as claimed are plant varieties (claims 1-3)

As aforementioned, Article 4.1 (a) of the EU patent directive 98/44 prohibits patents on plant varieties, while Article 4.2 allows patents on inventions concerning plants or animals if the technical feasibility of the invention is not confined to a particular variety.

Article 4.2 provides the main justification for the European Patent Office (EPO) to currently grant patents on plants and animals derived from genetic engineering. The exemption from the exclusion in Article 53 (b) is also part of the Implementation Regulation of the European Patent Convention, as established in Rule 27 b). This legal approach forms part of the G1/98 decision taken by the Enlarged Board of Appeal. It is regarded as a precedent for the patenting of genetically engineered plants and animals under the EPC – and is a ruling made shortly after the inclusion of EU Directive 98/44 into the Implementation Regulation of the EPC.

However, in the field of conventional breeding, there are several reasons why the exemption (Art 4.2 of 98/44) from prohibition in Article 53(b) cannot be used to allow patents on all plants and animals:

(1) As a general rule, this exemption cannot be applied to conventional breeding since the whole rationale of the EU Directive is based upon “biotechnological inventions”, and thus extends to the field of “genetic engineering” (see point above).

(2) If the “technical feasibility” (which should not be confined to a particular plant variety to fall under patent protection) is put in context of the processes for genetic engineering, which enables the technical insertion and transfer of DNA sequences, for example, also beyond the boundaries of species, the exemption from the exclusion (Art 4.2, from 98/44) develops a specific meaning. However, in conventional breeding most plant characteristics can be transmitted to another variety within the same species simply by using further breeding, without using a specific technology. As a result, the criterion retained in Article 4.2 (98/44) and applied by the EPO to restrict the exception to patentability, does not have a specific technical meaning in the context of conventional breeding and cannot be used as a legal basis to grant patents.

To summarize, the criterion of “confinement of the technical feasibility of the invention to a particular plant or animal variety” cannot be applied in the field of conventional breeding. If the provisions of Article 4.2 of EU Directive 98/44 were applied to plants derived from conventional breeding in the same way as they are applied to genetically engineered plants, the prohibition of patenting plant varieties would become meaningless.

Therefore, in the case of conventionally-bred plant and animal varieties, the prohibition of Article 53 (b) is not limited by Article 4.2 of the EU patent directive. Consequently, the ‘exemption to prohibition’ as established in Rule 27 (b) (EPC) cannot be applied in the case of conventionally-bred plants.

This has a substantial impact on the examination of patents in the field of conventional breeding. The definition of plant varieties provided by the EPC. Rule 26 (4) reads: “*‘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." It cannot be denied that, e. g., cold-tolerant maize plants such as those claimed in EP3380618 fulfill this definition. Therefore, the patent that was granted in contradiction to the EPC must be revoked.

1.3 The patent claims essentially biological methods (claims 3-6)

The history and the context of the technical development (above) shows that the need for EU patent directive 98/44 would never have arisen without the (at that time) new methods of genetic engineering - which for the first time allowed direct and technical insertion of traits into the genome of plants and animals. This is also reflected in decisions taken by the Enlarged Board of Appeal, which is the highest legal decision- making body of the EPO.

In its G2/07 and G1/08 decisions, the Enlarged Board of Appeal at the EPO, emphasizes the fundamental differences between genetic engineering and conventional breeding methods. In order to assess whether a process is eligible for patent protection, the Enlarged Board of Appeal applies the following considerations: "*This is the case, for example, for 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 (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.*" (emphasis added)

Consequently, the headnote of decisions G2/07 and G1/08 defines the decisive criteria as a technical step that allows the direct insertion of a trait: "*3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.*" (emphasis added)

Accordingly, the only thing needed to overcome the prohibition in Article 53(b) is a technical step within the process that directly and purposefully establishes a desired trait (defined phenotype) in the genome, and thus makes it fundamentally different to conventional breeding methods. A clear distinction between 'essentially biological' processes (conventional breeding) and technical inventions (methods of genetic engineering) is therefore easily made, as shown below:

(1) Essentially biological processes:

> Conventional breeding starts with a broad range of genetic diversity, followed by further crossing and selection. If methods such as irradiation are used for random mutagenesis, this does not change the overall process: broadly speaking, physico-chemical mutagenesis just triggers genomic changes in a non-targeted way to enhance genetic diversity in the plant material, which is needed for further steps of crossing and selection. Therefore, to establish a desired trait after random mutagenesis, the process will always, explicitly or implicitly, include sexual crossing and selection processes. Furthermore, the results of these processes are technically neither determined nor predictable, but largely impacted by the biological processes in the cells.[1] In conclusion, even if a step to trigger random mutations is introduced, the overall process still cannot escape the prohibition in Article 53(b). There is

[1] See for example: Monroe G., et al. (2022) Mutation bias reflects natural selection in Arabidopsis thaliana. Nature, https://doi.org/10.1038/s41586-021-04269-6

no doubt that, in light of the G2/07 and G1/08 decisions, such processes must still be considered to be ‘essentially biological’.

(2) Technical inventions:

On the other hand, technical genetic engineering methods involve the insertion of additional DNA sequences or the usage of biotechnological mutagens, and therefore allow the direct and targeted change of specific genes in the genome. These techniques not only result in alterations in the genome, but also enable the direct introduction of defined biological characteristics (phenotypes), so-called ‘traits’, into existing varieties. To achieve these goals, genetic engineering typically uses genetic constructs which, e. g. consist of promotors, start and stop codons and gene sequences optimized for expression in the plant cells. Furthermore, genome engineering techniques can also introduce specific and targeted changes in the genome by using biotechnological mutagens, such as CRISPR/Cas. These techniques can typically eliminate the steps of crossing and selection needed to establish a desired trait. Therefore, these genomic techniques can be considered to fulfill the criteria of a technical invention as established in the G2/07 and G1/08 decisions, while processes using tools such as irradiation cannot escape the prohibitions in Article 53(b).

In conclusion, in order to correctly apply the EU patent directive and its effects on the interpretation of the EPC, all exemptions to the exceptions to patentability of Art. 53(b) have to be contextualized within history and technical developments. The concept of a ‘technical invention’ has to be defined with reference to the ability to directly insert a desired trait into the genome of a plant or animal with a targeted technical process. This is in line with a historical interpretation of EU Directive 98/44 which was intended to allow patents on transgenic plants and animals.

Headnotes 1 and 2 of the G1/08 and G2/07 decisions have 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.”

1.4 Summary of grounds for opposition under 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 exceptions from the prohibitions in Art 53 (b) cannot be applied. As a result, the patent claims 1-6 are in contradiction to the EPC and have to be revoked.

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

According to the patent description, the claimed plants (claims 1-3) were already in existence: as explained in the examples (page 23, [0088]), cold-tolerant lines were the starting point for further phenotypical assessment and genotyping. Furthermore, on page 27 [0107], it is stated that the

analysis of the existing breeding population showed that 86% of the existing ‘dent population’ inherits the described QTL.

To imply novelty, KWS argues (letter from December 8) that additional markers (SNPs) will be present in the plants compared to the donor plants derived from further crossings. The SNPs listed in the claims do not have a specific biological function, they appear to be arbitrarily chosen genetic variants. KWS suggests that these SNPs indicate a disruption of a genetic linkage on Chromosome 4. Therefore, the claimed plants are supposed to only inherit the desired QTL, but not a specific centromeric region of the donor plants. The patent holder assumes this centromeric region may be potentially disadvantageous to further breeding, as such regions are associated with a low number of allelic variations.

However, these details are not sufficient to describe and construct novelty or a technical invention. This is because, in the first instance, the plants are obtained from standard conventional breeding methods and, due to sexual recombination, will always inherit genetic variants that are different to those of the donor plants. Secondly, the assumed linkage drag and its potentially disadvantageous effects was not characterized in any detail, it is simply a theoretical description of general biological features long known to be associated with centromeric regions. This fails to show that the claimed plants have other biological characteristics compared to varieties that are already on the market. Thirdly, as the examples show, the assumed genetic linkage drag did not raise any specific problems and was solved without the need to apply targeted technical methods, such as site directed nucleases.

In summary, the claimed plants (claim 1-3) are not well characterised by technical features. Arbitrary genetic changes that follow a statistical likelihood are a typical feature in all conventional breeding processes and, therefore, insufficient to produce plants that go beyond state-of-the-art plant breeding.

Furthermore, since KWS has been active in the breeding and marketing of cold-tolerant varieties for many years, it has to be assumed that the genotype present in the claimed plants can also be found in many varieties already on the market and freely available. Since Claim 1 comprises all maize plants with the desired allelic combination, these already existing plants and plant varieties would fall within the scope of the claims.

Therefore, the claimed plants are not new and cannot be regarded as a technical invention, they are simply based on a non-patentable finding and not novel.

3. The plants (claims 1-3) and processes (claims 4-6) are not inventive and therefore violate Article 56, EPC

From the filed examination of the process, it is evident that documents, such as D2-D4, which were discussed and summarized by the EPO in their communication from 30.3.2021, already provided knowledge about a QTL on chromosome 4 which was associated with cold tolerance. The patent holder and the EPO both agree that this is the same QTL which was used to produce the plants claimed in the patent.

Therefore, to imply inventiveness, KWS argues (letter of December 8) that additional markers (SNPs) will be present in the plants compared to the donor plants which are derived from further crossings. The SNPs as listed in the claims do not have a specific biological function, they simply

appear to be arbitrarily chosen genetic variants. However, KWS suggests that these SNPs indicate a disruption of a genetic linkage on chromosome 4 between the QTL and the centromeric region.

The patent holder assumes that this centromeric region may be potentially disadvantageous for further breeding, as such regions may be associated with a low number of allelic variations.

KWS uses markers for selection to perform segregation breeding to dissect the centromeric region from the desired QTL – these markers are presumed to not include the undesirable parts of the centromeric region on chromosome 4. As a result, the claimed plants are supposed to only inherit the desired QTL, but not a specific centromeric region of the donor plants.

However, these details are insufficient to argue inventiveness: first of all, due to sexual recombination, plants derived from standard conventional breeding methods will always inherit genetic variants that are different to those of the donor plants. Secondly, the assumed linkage drag and its potentially disadvantageous effects was not characterized in any detail, it is just a theoretical description of biological features associated with centromeric regions. Therefore, it is not shown that the claimed plants have biological characteristics that are inventive compared to varieties that are already on the market. Thirdly, as the examples show, the assumed genetic linkage drag did not raise any specific problems and was dissolved without the need to apply targeted technical methods such as site directed nucleases.

Therefore, the supposed inventiveness is simply a matter of statistical frequency, which is an issue for all non-targeted mutations. In summary, the inventiveness of the patent is not well characterised by technical features. Arbitrary genetic changes that follow a statistical likelihood are a typical feature in all conventional breeding processes and, therefore, not sufficient to claim these plants as an invention.

The patent holder seems to be aware of this problem and subsequently added a further detail in Claims 2 and 6 which states: "*characterized in that the region on chromosome 4 flanked by the marker positions ma59778119 and ma20205s01 has an enhanced allele frequency, at least in parts*". (Original German version: "(…) dadurch gekennzeichnet, dass der Bereich auf Chromosom 4 flankiert durch die Markerpositionen ma59778119 und ma20205s01 zumindest in Teilen eine erhöhte Allelfrequenz aufweist.")

It should be well understood by all experts that such a vague qualitative description does not add anything substantial to overcome the lack of inventiveness.

4. Grounds for opposition under Art 83, EPC

The characterisation of the claimed plants and the methods used for their detection is based on genetic information considered to be a QTL. Several markers are listed with several options for relevant alleles that maybe be helpful to distinguish the plants. The tests that have to be carried out to identify the desired plants are complex and based on unclear terminology and wording, such as in Claim 1, which is based on a large number of technical details – not all of these seem to be useful, necessary or sufficient, and could be used alone or in combination. The claim states:

"(…) nucleic acid, wherein the chill tolerance-conferring nucleic acid comprises a nucleic acid sequence selected from the group consisting of
a) a nucleic acid sequence with SEQ ID NO: 29,
b) a nucleic acid sequence which has at least 98% identity with a sequence from a),

c) a nucleic acid sequence which differs from a nucleic acid sequence according to a) in accordance with the degeneracy of the genetic code,
d) a nucleic acid sequence which codes for a protein with SEQ ID NO 30,40
wherein a T is at the marker position ma59778s31, a T is at a marker position ma59778s32, a C is at the marker position ma59778119, an A is at a marker position ma52594s01 and a G is at a marker position ma20205s01, or wherein a C is at the marker position ma59778s31, a T is at a marker position ma59778s32, a C is at the marker position ma59778119 and an A is at a marker position ma52594s01; and wherein the marker positions with reference to the maize line B73 AGPv2 are as follows: ma59778s31= 37263172 bp, ma59778s32 = 37296672 bp, ma59778119 = 37297901 bp, ma52594s01 = 58033711 bp and ma20205s01 = 156998152 bp."

Original German version:

"(…) wobei die Kühletoleranz-vermittelnde Nukleinsäure eine Nukleinsäuresequenz umfasst, ausgewählt aus der Gruppe bestehend aus
a) einer Nukleinsäuresequenz gemäß SEQ ID NO: 29,
b) einer Nukleinsäuresequenz, die zu mindestens 98% identisch ist mit einer Sequenz aus a),
c) einer Nukleinsäuresequenz, die sich entsprechend des degenerierten genetischen Codes von einer Nukleinsäuresequenz gemäß a) ableitet,
d) einer Nukleinsäuresequenz, die für ein Protein gemäß SEQ ID NO 30 kodiert,
wobei an der Markerposition ma59778s31 ein T, an einer Markerposition ma59778s32 ein T, an der Markerposition ma59778119 ein C, an einer Markerposition ma52594s01 ein A und einer Markerposition ma20205s01 ein G ist, oder wobei an der Markerposition ma59778s31 ein C, an einer Markerposition ma59778s32 ein T, an der Markerposition ma59778119 ein C und an einer Markerposition ma52594s01 ein A ist; und wobei die Markerpositionen mit Referenz zur Maislinie B73 AGPv2 die folgenden sind: ma59778s31 = 37263172 bp, ma59778s32 = 37296672 bp, ma59778119 = 37297901 bp, ma52594s01 = 58033711 bp und ma20205s01 = 156.998.152 bp."

Claim 4 uses the same technical elements, but in a slightly different order.

The preparation for this opposition included cooperating with maize breeders and a laboratory that are well experienced in genome analysis, as we wanted to find out whether the technical description is sufficient to enable breeders (who are the experts in the field) to identify the desired traits within a given gene pool. However, neither the laboratory nor the breeders were able to identify the relevant plants. They were also not able to identify other laboratories or breeders that could provide any such services. Some other experts we interviewed found the way in which the technical elements are presented confusing and not suited for practical application. There are several reasons for this problem, e. g. giving several options and genetic variations that may or may not be fulfilled. Furthermore, the specific marker positions are only described in regard to the specific reference line B73 AGPv2 and can be difficult to compare with other lines and varieties. Furthermore, vague descriptions, such as "enhanced allele frequency, at least in parts", lack a sufficiently clear technical definition.

Therefore, the patent does not overcome the requirements of Art 83, as it does not enable the experts in the field to identify the plants as claimed in a given gene pool under realistic conditions.

4. Grounds for opposition under Art 53 (a), EPC

As described above, the plants with the described genotype and phenotype are likely to be present in several plant varieties on the market.

In effect, this patent claims the future usage of all the described plant material as the monopoly of the patent holder. This creates major obstacles for all maize breeders: there is huge uncertainty as to whether specific varieties inherit the genotype as claimed or not. Consequently, other breeders may have to stop further breeding to produce and market new varieties as guaranteed under the breeders' privilege. This problem may even affect their own varieties obtained from a previous breeding process if any plant material described in the patent was used.

In effect, this patent will hamper or even block access to the biological resources needed by other breeders to develop new maize varieties with cold tolerance. Therefore, this patent presents an existential a threat to all breeders active in the field who rely on the freedom to operate using existing varieties to produce new varieties needed to face present and future challenges. Beyond that, besides impacting farmers, it could also severely impact our future food security and food sovereignty.

Thus, in general, from the perspective of 'ordre public' or morality in Europe these patents with claims covering natural biological resources needed for future food production are completely unacceptable.

Annex:

Correct legal interpretation of Article 53(b), EPC, within the context of the EU patent directive 98/44