

August 2011

UFS position on Innovation Protection in plant breeding

Requirement for strong protection and possible paths towards a harmonious co-existence of protection systems

Preamble:

UFS affirms that the regular genetic progress made by our industry is based on access to and use of genetic variability for all and by all.

Innovation is at the heart of the seed industry. The breeder has always striven to improve vegetal material provided for farmers, which ultimately has been for the benefit of all consumers.

Genetic progress through plant breeding is an important part of food policy. It helps to provide diversified and safe quality food for the whole population.

This genetic progress requires the maintenance of and access to a significant level of diversity. This is the essence of breeders' profession and a real collective wealth. Every year, about 600 new seed varieties are placed at the farmers' disposal.

Therefore, UFS is particularly attached to preserving access to and maintaining this diversity which allows continued genetic progress.

Genetic progress achieved by the seed industry is undeniable, as much from an agronomic, quality or environmental point of view, especially these last decades.

This progress reflects the significant investment breeders have made in research & development (either through conventional selection methods or with the contribution of biotechnology), which represents up to 12 to 15 % of their turnover.

In order generate a fair return on investment, innovation needs to benefit from forms of legal protection which are best suited to our profession.

This protection is the best guarantee of continuity in research efforts and in the long term of the benefits of genetic progress for all.

- **Argument for protection by the Plant Variety Protection Certificate:**

UFS is particularly attached to preserving access as well as the possibility of using genetic variability allowed by the current International Convention for the Protection of New Varieties of Plants (UPOV) through the Plant Variety Protection Certificate.

UFS supports UPOV rights and more specifically the UPOV1991 convention. UFS acknowledges the Plant Variety Protection Certificate as the only plant variety protection system in Europe.

In the field of plant breeding, a sui generis right has been developed since 1961 by the International Convention for the Protection of new Varieties of Plants (UPOV).

Existing protection systems were not suitable for plants; a specific law adapted to breeding new varieties was adopted, designed to apply to living material and thus safeguarding improvements in varieties. This protects a unique genetic combination achieved by Research undertaken by the breeder.

In this way, any plant variety can benefit from a protection which gives its holder an exclusive right to carry out certain actions (to produce, condition, market, sell) and at the same time leaves the variety available, free from restrictions, for research and in particular plant breeding, which includes of course the creation of new varieties.

This particular feature of the Plant Variety Protection (PVP) Certificate is known as “Breeder’s right”.

The act of 1991 has reinforced the rights of the breeder by extending them to varieties essentially derived from the breeder’s variety, thus protecting the breeder from a simple copycat of his variety.

UFS is strongly attached to the UPOV convention, in particular to its revised version of 1991 and the breeder’s right.

- **Argument for protection by patent:**

UFS also acknowledges the interest of protection of biotechnological inventions through patents, generally recognized as efficient in supporting those inventions.

Breeders not only create varieties, they also develop new procedures and techniques with a view to obtaining varieties which are even better suited to users’ needs.

Progress in biotechnology has thus opened new fields of innovation. The worldwide development of plants created by biotechnologies shows how agriculture can benefit from these technological feats.

As with any form of invention, biotechnological plant inventions need to be protected by appropriate means.

Patent law as defined by the European directive 98/44 (6 July 1998) allows the protection of innovations in the vegetal field, permitted by technical evolutions over the years, on condition, of course, that these innovations meet patent criteria. In this way a gene whose function has been modified or a technical procedure, if it is not essentially biological, can be patented.

Many patents have already been granted for interesting and beneficial improvements such as tolerance to insects or herbicides by certain plants, or a production method of cucumber haploids.

- **Interference between PVP Certificate / patent and proposition for a harmonious co-existence:**

The seed industry can use both protection methods in a complementary way, the Plant Variety Certificate and the patent of biotechnological innovations. The object of each protection being different, one (PVP Certificate) protecting a genetic combination as a whole, the other (patent) protecting one particular and limited element of the combination, both methods of protection are

necessary. Nevertheless, they can overlap, as one variety protected by PVP Certificate can also be obtained by a patent process and/or contain several patented elements. This is for example the case for hybrid rape varieties using the hybridity system patented by INRA.

This requires special attention to certain matters such as:

- Uncertainty about granting a right and its subsequent scope
- Access to genetic background
- Information of users (transparency)

UFS wishes for a balanced coexistence of both systems so that uncertainties about the patent for the profession of breeder can be limited.

UFS recommends the following solutions:

1. Uncertainty about granting and scope of the right:

Uncertainties exist for the depositor and the third party affected (mainly the community of breeders). The aim is to be able to influence the relationship between the depositor and the examiner, in order to improve the practices of the former and to facilitate the activity of the latter.

If precise rules cannot be defined within the examination board because each application for a patent is a special case, it seems essential to help the examiner diminish uncertainty and speed up the procedure.

In this field, the community of breeders needs to participate in broadening the knowledge of examiners, so that they can fully appreciate the expertise of the breeders' profession.

In this sense, our International associations, the International Seed Federation (ISF) and the European Seed Association (ESA), have done an important bibliographic job and have organized regular meetings with patent offices notably the European Patent Office (EPO).

The members of UFS strongly support this approach.

As a practical step, UFS wishes to provide its members with a good practice guide for patent applications.

Often quite **broad claims** are linked to the application for a patent. UFS wishes that these claims be granted up to a limited extent only, so that other breeders are not unduly restricted in their capacity for innovation. This question is closely linked to the state of knowledge at the time of the submission of the application and also to the evaluation of the criterion of inventiveness. UFS would like to avoid any possible blocking or restriction to genetic variability.

For this purpose, UFS advocates the drafting of a position paper warning about broad claims.

2. Uncertainty about the status of the variety to be put on the market:

Is the variety put on the market covered by one or more patents?

This uncertainty, created by pending or delivered patents, stems from the fact that patents can apply to plants in general and not to varieties, and that it can be difficult to establish a link between a specific variety which has been put on the market and the plants concerned by the corresponding patent(s). Another factor of uncertainty is the fact that patent claims can be rejected on the basis of appeals from third parties, even after the patent has been delivered. This makes the limits of the patent uncertain for many years. Transparency concerning the link variety – patent(s) is therefore essential for the use of genetic variability, as it is needed in breeding.

In order to move towards more transparency about the status of varieties, and also to clarify certain legal questions, UFS declares itself in favour of a public information policy:

- **The creation of a database containing, for each variety put on the market, the link to publicized applications for patents and to any relevant granted patents the breeder knows of.**
- **This data should be consultable on a website where each breeder can view the situation of any variety marketed, if concerned by the presence of any patented elements.**

Practical aspects should be discussed within breeders' representative associations and should particularly deal with the delicate question of updating the database during the 18 months before publication of the patent application.

3. Uncertainty concerning the scope of patentability:

UFS believes that patentability should be restricted to genuine inventions. Therefore, UFS is opposed to granting patents:

- **when the invention comes down to simple discoveries,**
- **when the technical human intervention does not have a substantial impact on the product or the process the patent is destined to cover.**

For UFS, the discovery of a native gene and its function, defined or not by a sequence, or the discovery of an interesting genetic recombination inside a plant cannot be called an "invention".

In the view of UFS, the question of the status of genes / native traits is therefore essential.

UFS calls native traits all characteristics (phenotypes) of a given plant, conferred by one or more genetic elements which is itself/are themselves:

- a) naturally present (i.e. exist in the nature, in one individual of the species or a very close species) and recombined in the given plant by a sexual combination (with or without use of DNA markers) or
- b) obtained by a traditional selection method (which include and are not limited to random mutagenesis using chemical agents or ionizing beams, "tilling" methods).

To avoid uncertainty about the concept of "native feature", UFS considers that it does not apply when:

- a) genetic diversity has been created by biotechnological means including, but not limited to, directed mutagenesis, or cisgenesis,
- b) introgression in the plant by means of sexual crossing only is not possible and needs to be facilitated by other means such as protoplast fusion, transformation, deletion enzymes.

UFS considers that native traits and related native genes have to be excluded from patentability in order to preserve the use of genetic variability, and this with regard to the specificity of the profession, the basis of which is the recombination of native traits.

To achieve this, UFS prefers a self-regulation regime for breeders. It will however not refrain from engaging with the Authorities to achieve its aims if a consensus cannot be obtained within the profession.

UFS states that it is clearly against patentability of native traits and genes and wishes that this position be adopted by the entire seed industry. For this purpose, a code of conduct would guarantee a solid position within the profession. Otherwise, UFS will take the necessary steps to get its position accepted, if need be through regulatory means.

- **Breeder's rights:**

UFS is strongly attached to the possibility of maintaining access to the genetic material of a variety containing a patented element. UFS supports the disposition introduced into the French and German implementation of the European directive on biotechnological inventions, which allows the breeder to use any variety containing patented elements free of duties on sale if in the end, the new variety obtained no longer contains these patented elements.

UFS supports breeder's rights as stated in the French & German implementation of the European directive on biotechnological inventions. We will support any demand to extend this disposition to other European countries.

- **Food for thought for the future:**

UFS will be particularly vigilant regarding the restrictive impact of a multiplication of patents for one and the same variety on access to and use of genetic variability. Such a development could technically make breeder's rights obsolete. UFS considers that access to genetic variability is a principle whose importance goes beyond individual interests and could reconsider its position if such developments occurred.

UFS remains convinced that the Plant Variety Certificate is and will be the most appropriate protection for varietal creation. We are aware of the number of questions legitimately asked with regard to patents for biotechnological inventions. UFS, in addition to its current position, recommends the opening of discussions on the background of the question in order to progress this sui-generis protection system for vegetal breeding and to adapt it to technological developments and to make it stronger, so that it can continue to be the motor of plant breeding.

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| UFS POSITION ON INNOVATION PROTECTION IN PLANT BREEDING |
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UFS is particularly attached to preserving access as well as the possibility of using genetic variability given by the International Convention for the Protection of New Varieties of Plants (UPOV) by means of the Plant Variety Protection Certificate.

UFS supports UPOV rights and more specifically the UPOV 1991 convention. UFS recognizes the Plant Variety Protection Certificate as the only plant variety protection system in Europe.

UFS also acknowledges the interest of protection of biotechnological inventions through patents, generally recognized as efficient in supporting those inventions.

UFS wishes for a balanced coexistence of both systems so that uncertainties about the patent for the trade of breeder can be limited.

UFS recommends the following solutions:

- **As a practical step, UFS wishes to provide its members with a good practice guide for patent applications.**
- **UFS advocates the drafting of a position paper warning about broad claims.**
- **In order to move towards more transparency about the status of varieties, and also to clarify certain legal questions, UFS declares itself in favour of a public information policy:**
 - **The creation of a database containing, for each variety put on the market, the link to publicized applications for patents and to any relevant granted patents the breeder knows of.**
 - **This data should be consultable on a website where each breeder can view the situation of any variety marketed, if concerned by the presence of any patented elements.**

UFS states that it is clearly against patentability of native traits and genes and wishes that this position be adopted by the entire seed industry. For this purpose, a code of conduct would guarantee a solid position within the profession. Otherwise, UFS will take the necessary steps to get its position accepted, if need be through regulatory means.

UFS supports breeder's rights as stated in French & German implementation of the European directive on biotechnological inventions. We will support any demand to extend this disposition to other European countries.

Finally, UFS is prepared to participate in any reflection on the development of the UPOV system which strengthens its role of protecting vegetal inventions.

UFS is a trade association which represents the interests of the Seed Industry and promotes plant breeding in France and Worldwide. UFS brings together 135 French seed companies involved in breeding, production and marketing of seeds for agriculture, gardens and landscape.