

Discussion Paper

Access to Plant Genetic Resources and Intellectual Property

Plant Variety protection outside the European Union

and

Protection of Plant Varieties by Utility
Patents

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ESA Mission Statement

ESA is the voice of the European seed industry, representing the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species.

Plants from seed are the origin of all food, provide innovative and environmentally friendly industrial products and beautify our landscape.

ESA's mission is to work for:

- ◆ effective protection of intellectual property rights relating to plants and seeds;
- ◆ fair and proportionate regulation of the European seed industry;
- ◆ freedom of choice for customers (farmers, growers, industry, consumers) in supplying seeds as a result of innovative, diverse technologies and production methods

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Part A

General Introduction

It is an important part of ESA's mission to contribute to the availability of effective and efficient plant variety protection to the creators of new plant varieties.

In doing so, ESA works for harmonised preconditions, scope and enforceability of the different available systems for the protection of intellectual property for plant varieties throughout the world.

In this discussion paper, ESA tries to analyse UPOV based plant variety protection outside the European Union as well as the protection of plant varieties by utility patents.

Based on ESA's Position Paper on Access to Plant Genetic Resources and Intellectual Property in the European Union (v. ESA_04.0056.2), this discussion document concentrates on ESA's understanding and analysis of actual and/or perceived strengths, weaknesses and deficiencies of these non-EU systems.

In view of the European seed industry's commitment to a harmonised and commonly agreed approach to important issues such as biodiversity, benefit sharing, farmers' rights and traditional indigenous knowledge which are currently discussed at national, European and international level, ESA is convinced that a better mutual understanding of the different existing approaches to access to plant genetic resources and intellectual property is crucial.

With this discussion paper, ESA wants to put forward its current interpretation and perception of some of the most important features of systems for plant variety protection outside the European Union. This interpretation and perception shall help to define issues for further discussion with ESA's colleagues worldwide. The aim of this document therefore is not to put forward a final position of the joint European seed industry but to stimulate the further debate with our colleagues from other parts of the world and to contribute to the seed industry's common goal, the mutual strive for adequate protection of its intellectual property whilst at the same time encouraging further research and development by assuring the necessary access to plant genetic resources for the breeding of new plant varieties.

Part B

UPOV Plant Variety Protection outside Europe

1. Introduction

ESA has clearly stated that the 1991 Act of the Convention for the Protection of New Varieties of Plants (UPOV) is the most suitable existing sui generis intellectual property system for the protection of plant varieties per se¹ but it is ESA's conviction, too, that UPOV 1991 can only develop the effects that are beneficial for its users if properly implemented.

ESA has identified a number of weaknesses in different national UPOV based plant variety protection systems outside the European Union.

These deficiencies are highlighted in confronting them with the respective provisions of the Community Plant Variety Right (CPVR), since it is ESA's conviction that the CPVR system is the most appropriate implementation of UPOV 1991.

2. Object of protection

ESA is of the opinion that Plant Breeders' Rights (PBR) should be offered to all kinds of plant varieties and should not be restricted to plant varieties that are sexually reproduced or tuber-propagated.

CPVR offers protection for all genera and species irrespective the propagation method.

3. Duration of protection

ESA is of the opinion that the protection of 20 years for most crops and 25 years for trees, shrubs and vines is the utmost minimum period following UPOV and does not correspond to the real need of the holders of the right.

CPVR provides for a duration of protection of 30 years for trees, vine and potatoes and of 25 years for all other crops.

4. Breeder's exception

ESA is of the opinion that a breeder's exception allowing only the use and reproduction for breeding to develop a new variety does not comply with UPOV 1991 because here also acts with the new developed variety referred to in Art. 14 (1) to (4) of UPOV 1991 with exception of essentially derived varieties are covered.

The breeder's exception of the CPVR allows acts done for the purpose of breeding or discovering and developing other varieties as well as acts of multiplication, conditioning, marketing etc. of such other varieties.

¹ ESA Position Paper ESA_04.0056.2

5. Farm saved seed exemption

ESA is of the opinion that a farm saved seed provision in the sense of a crop exemption allowing the saving of seed for the sole use of replanting the farmer's land and covering all crops without any provision in view of remuneration for such use of farm saved seed to be paid to the holder of the right does not comply with UPOV 1991.

Furthermore, any provision aiming at authorising farmers to sell farm saved seed goes far beyond the principles as set out in UPOV 1991 for this optional exception of the scope of PBR.

These UPOV principles state that this restriction to the PBR may be provided for within reasonable limits and subject to safeguarding the legitimate interest of breeders in order to permit the use of the harvested product on the farm for propagating purposes.

In the case of optionally available national as well as supranational systems for protection, it has to be assured that the contents and definitions in both systems must be consistent. This is clearly not the case when different definitions of so-called small farmers being exempt from the obligation to pay remuneration are laid down.

The farm saved seed provision (agricultural exemption) in the CPVR is restricted to well-defined agricultural plant species and their use for planting on the own holdings.

It provides for a remuneration to the holder of the right and for an exception of the payment obligation for small farmers.

6. Examination systems

ESA is of the opinion that in view of testing for Distinction, Uniformity and Stability (DUS), a computerised examination system using non-verifiable test data that are not comparable and that are provided by the applicants bears insufficiencies and deficiencies in view of the living nature of the matter to be tested, since no interactions resulting from differences in climate, soil, testing period and reference varieties can be taken into consideration.

ESA clearly favours the existing field-testing system under the CPVR, but underlines the need of having a cost effective, cost saving system for DUS testing in place.

7. Access to parental lines

ESA understands Art 15 (1) iii UPOV 1991 concerning acts done for the purpose of breeding other varieties and, with exception of essentially derived varieties, acts like production of marketing of propagating material of such new varieties as a definitive

regulation. In no case a positive right for claims and access to material of the protected variety is stated.

ESA is of the opinion that national laws providing for a positive right to claim access to protected parental lines of marketed hybrids is not compliant with the UPOV Convention Act 1991.

Part C

Protection of Plant Varieties by Utility Patents

1. Introduction

The European Patent Convention (EPC) excludes the patentability of plant varieties per se and essential biological processes for the breeding of plants (Art. 53 b EPC).

Outside the area of the EPC, in few countries patent protection for plant varieties is offered through specific Plant Patents and/or Utility Patents.

In both cases, the usual requirements for patentability, i.e. novelty, industrial application, enabling disclosure and non-obviousness must be met.

In the following, some specific discussion points are listed, highlighting the alleged advantages of Utility Protection for Plant Varieties and questions resulting from this.

2. Utility patents for plant varieties

2.1. Perceived advantages

The reasons for seeking patent protection for plant varieties are mainly explained by the broader scope of protection.

The interest for this lies with the

- needed balance of rights in view of the Convention on Biological Diversity (CBD) and the Food and Agricultural Organisation International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty on PGRFA)
- more stringent requirements for granting protection
- absence of a breeder's exception
- absence of a farm saved seed provision
- assured access to protected germplasm by disclosure and after protection.

2.1.1. Justification in view of balance of rights

The need for a stronger protection is justified by the supposed unbalance between existing PBR and the newly created legal mechanisms in the framework of the CBD. In the CBD, the national sovereignty on germplasm is confirmed and prior informed

consent as well as agreements on benefit sharing are required before the germplasm can be accessed.

Furthermore, as has been argued, the creation of the notion “farmers rights” has rendered the situation of breeders requesting access to plant genetic resources very difficult.

This would result in a decreased incentive to encourage further investments in maintaining a broad base of germplasm and in creating new and improved varieties. Without this incentive, however, as is concluded, it is unlikely that the goals of the CBD and/or the FAO Treaty on PGRFA to encourage sustainable conservation and use of a broader base of germplasm can be reached.

2.1.2. Justification in view of more stringent requirements

One main argument for justifying the stronger protection by utility patents is that the requirements for obtaining a utility patent, namely novelty, utility, disclosure by a full and enabling description and non-obviousness, are more stringent than the DUS requirements of the PBR. The full and enabling requirement means that a breeder must describe the plant variety with sufficient specificity to enable “a person skilled in the art” to “make and use” the invention.

It is argued that this stringent description requirement for plant varieties may be replaced by a deposit of biological material to a publicly accessible organisation.

2.1.3. Justification in view of absence of breeder’s exception

The absence of a breeder’s exception and the existence of a very narrow research exemption is highly welcomed by the owners of such patents, since it is argued that this principle would no more fit in the present technical, legal and economical context. The view is that the evolution in breeding techniques implies increasing costs in order to be increasingly innovative in less time. This acceleration of innovation would inevitably result in less time to recoup the investments. It is assumed that in order to avoid the steep increasing costs of breeding with sophisticated methods it would become common practice that competitors will make more and more use of existing protected varieties in order to profit from the achievements of the original breeders at a lower degree of innovative effort and at considerable lower costs.

By this, the genetic basis for innovation would consecutively become narrower parallel with the increasing difficulties to obtain access to plant genetic resources.

Furthermore, in view of patent holders, a breeder’s exception constitutes a general compulsory licence, which is not acceptable.

Therefore it is concluded that only a very narrow research exemption together with a broad scope of protection as provided for in the Utility Patent system could render the incentive needed in actual and future breeding work.

2.1.4. Justification in view of absence of a farm saved seed provision

Research is the precondition to innovation. The respective investments are long-term and bear high risks. It is generally recognized that the protection of intellectual property resulting from these innovations assure the return of the respective investments.

Only a strong protection with no exemptions for any specific professional or societal groups assures that investors would be able to recuperate the necessary returns on their risk capital.

2.1.5. Justification in view of access to protected germplasm

Access to protected germplasm by disclosure and after elapsed protection is brought forward as another argument in favour of protection by Utility Patents.

It is stated that parent lines in the PBR system, if not marketed as such, may, contrary to the Utility Patent system where a sample must be deposited at a publicly accessible organisation, never become publicly available and will remain at the exclusive disposition of the breeder.

After expiry of the patent protection, this deposited material will become publicly available and will contribute to broaden the available plant genetic resources.

Part D

ESA Discussion Points on Plant Variety Protection by Utility Patents

1. Scope

ESA considers the reasons and arguments brought forward as above in favour of the Utility Patent to protect plant varieties not convincing:

- The quoted unbalance between PBR and national sovereignty on germplasm, obligation for prior informed consent, benefit sharing mechanisms and farmer's rights is based on the inadmissible assumption that here two different systems of Intellectual Property are conflicting. This is, however, not the case since these CBD resulting elements and instruments are in no case individual intellectual property rights, but general obligations resulting from public law.

Insofar no argument for a justification of a broader scope of protection to be defined by claims compared to PBR can be drawn from this aspect whereas for the protection of inventions for properties within plants a broader scope of protection by generic claims is justified.

In any case, the point has to be made that the protection of plant varieties via Utility Patent with a broad scope of protection and without a breeder's exception and without balanced farmers' exemption renders the discussion for plant breeders in the framework of CBD, the FAO International Treaty on PGRFA and the World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property (TRIPS) difficult if not impossible.

- It is impossible to know in each case what the scope of patent protection really is, because the claims do not give sufficient information about the elements that are essential for the invention. Certain patent examiners assume that claims relating to a plant variety are limited to the claimed deposited line, i.e., that the claims are not broader than the seed/plant represented by the deposit.
- In this respect claims for deposited material extending to an undefined and non-described progeny or any line/variety distinct from such deposited material are clearly unacceptable.
- Although broad progeny claims have been declared unacceptable by certain Patent Offices, it is not clear whether the still existing patents with broad claims would be enforceable or whether applicant(s) will be able to

appeal against a possible rejection of such claims. Legal certainty can only be obtained by court decisions.

- Product by process claims with no clear specification as to the resulting products will create further legal uncertainty, especially with respect to the import of material of plant varieties bred outside the country granting the patent but for which possibly patented germplasm was used.

2. Requirements

- Novelty of a claimed plant variety cannot be properly assessed. The applicant seldom specifies which elements or combination of elements are essential for the novelty of a plant variety. Without such information, a patent examiner cannot establish whether the deposited line or plant is novel. It is interesting that Plant Variety Protection Offices require information about the pedigree in order to assess novelty of a plant variety while Patent Offices do in general not and do not use any database of Plant Variety Protection Offices.

Because each plant variety is regarded as the unexpected result of an obvious (plant breeding) process, the criterion of non-obviousness is according to pending practice assumed to be fulfilled if the examiner is satisfied that the novelty criterion is met.

This is clearly not in line with existing guidelines for plant patents. Also, because the non-obviousness has to be judged against the existing prior art the applicant has to supply information about relevant prior art. This requirement is rarely met.

- The description requirement can not be satisfied solely by the deposit of the biological final product, since it is usually defined in that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the invention.
- A deposit is rather meaningless at least for products that are intended to be commercially available.

3. Research exemption

- Taking the application of new and highly costly, sophisticated breeding methods as the justification for a narrow research exemption as to patented plant varieties is not convincing. If there is really a new sophisticated method, than the certainly available patent protection of this technology does provide for sufficient protection and guarantees the

necessary return on investment. No justification for excluding plant varieties bred with such technology from the area of accessible plant genetic resources by not providing for a breeder's exception can be seen. Moreover, for the time being the plant varieties actually protected by utility patent have all been bred by traditional, obvious methods.

4. Access to genetic resources

- The genetic resources in view of parent lines in the PBR system generally are publicly available in the form of the marketed hybrid. In the Utility Patent system it is at least doubtful, whether the protected invention, due to the limited duration of the patent, will be put in the public domain. The written description (enabling disclosure) or the deposit and the non-obvious clause for utility patents are in most cases not really accomplished or at least doubtful. Therefore a discrepancy between the scope of the right and what is being disclosed cannot be excluded.