

27. Dez. 2007



International Seed Federation

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Nyon, 21 December 2007
BLB/mp

Case I.83/05 (Amicus curiae)

Dear Mr. Roepstorff,

The International Seed Federation (ISF) appreciates the opportunity offered to third parties to file a written statement in accordance with Article 11(b) of the Rules of Procedure of the Enlarged Board of Appeal (EBA) regarding the questions of law that the Technical Board of Appeal has referred to the EBA with interlocutory decision of May 22, 2007 in case I.83/05.

With members spread over 70 developed and developing countries on all continents, ISF represents the mainstream of the world seed trade and plant breeders community, and serves as an international forum where issues of interest to the world seed industry are discussed.

The two questions asked by the EBA are:

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants 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, an additional feature of a technical nature?
2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

The answers of the ISF Breeders Committee are as follows:

Answer to question 1

The important word of question 1 is "merely" without qualification of the additional feature of technical nature.

In those conditions, the answer to question 1 is "no".

Answer to question 2

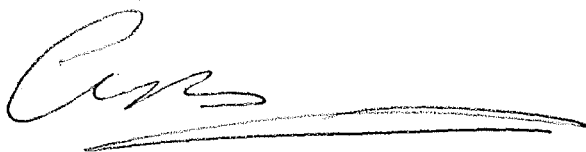
ISF members consider that a non-microbiological process for the production of plants, in the meaning of the development of a new variety, which contains the steps of crossing and selecting plants, should not be excluded from patentability by Article 53(b) EPC if it contains, as a further step or as a part of the steps of crossing and selection, a process representing a technical teaching.

To fulfill the requirement of a technical teaching that further step or that part of the steps of crossing and selection must solve a technical problem and be material to the process or, in other words, that without that step the claimed process would not have achieved its intended result.

It must be noted that the fact that a claim is not excluded from patentability by Article 53(b) does not imply that a patent should be granted to that claim. The general requirements of patentability, novelty, inventive step and sufficient disclosure also have to be fulfilled.

For more information on ISF View on Intellectual Property and in particular on protection of biotechnological inventions (chapter 2 of the enclosed document), please find enclosed the position adopted by ISF members in 2003.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Bernard Le Buanec', followed by a long horizontal line.

Bernard Le Buanec
Secretary General

Enc.

ISF View on Intellectual Property
(Bangalore, June 2003)

Setting the Scene

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ISF View on Intellectual Property¹

Setting the Scene

ISF members are unanimously in favor of a strong and effective intellectual property protection necessary to ensure an acceptable return on research investment, prerequisite to encourage further research efforts, essential to meet the challenges mankind has to face in the coming years, i.e. feeding an increasing population whilst preserving the planet. These challenges cannot be met without further development of new knowledge, technologies and the more effective use of a broader base of genetic resources. All of these endeavors require substantial, long-term and high risk investments.

For plant varieties, the type of protection that is currently available varies according to the technical, legal and socio-economic status of the various countries. In all the countries, where plant varieties are protectable, a UPOV² or UPOV-like system is available. There are a few countries where protection through utility patents is also possible. ISF considers that both systems are legitimate. If a country envisages the adoption of a *sui generis* system to protect plant varieties ISF recommends that this *sui generis* system, as a minimum, conform to the requirements of the 1991 Act of the UPOV Convention.

The patent system also provides an appropriate protection for biotechnological inventions. In the future, the benefits of the different systems available in various countries could be evaluated and balanced into a strong intellectual property protection system that would serve to encourage the improvement of varieties using both conventional and biotechnological genetics.

1. Protection of plant varieties through Breeder's Right

1.1 What is plant breeding ?

Plant breeding, very briefly, is developing new varieties through the creation of new genetic diversity by the reassembling of existing diversity with the aid of all available technologies and using strategies based upon knowledge from basic research.

Plant breeding, regardless of whether it is carried out by the public or the private sectors, requires significant human resources from many skill areas and financial investments to support the lengthy and risky processes of research and product development.

Plant varieties are protectable generally by a *sui generis* system and in some countries by patents. ISF considers that the UPOV Convention, and particularly its 1991 Act is an effective *sui generis* system for the protection of plant varieties. In addition to novelty and acceptable denomination, the three criteria a variety has to fulfill to be protectable are Distinctness, Uniformity and Stability, known as DUS. The three criteria are equally important.

1.1 Conditions for the granting of Breeder's Right

According to the UPOV Convention, for a variety to be protected, it must be:

- new
- distinct
- uniform

¹ ISF recognizes that, given all relevant prevailing and future factors, this document may necessarily be subjected to evolutionary modifications.

² UPOV: Union pour la Protection des Obtentions Végétales (International Union for the Protection of New Varieties of Plants)

- stable
- designated by an "acceptable designation".

The grant of the Breeder's Right shall not be subject to any further or different conditions.

1.2.1 DUS Testing

1.2.1.1 Characteristics for DUS testing

1.2.1.1.1 Basic conditions that a characteristic should fulfill to be used for the purpose of DUS testing

ISF fully supports the provisions provided for by UPOV as regards characteristics for DUS testing.

For ISF, these principles guarantee the quality and the pertinence of the Breeder's Right because they define the basic conditions that a characteristic should fulfill to be used for the purposes of DUS testing. The basic conditions are that a characteristic should:

- a. result from a given genotype or combination of genotypes
(this requirement is specified in Article 1(vi) of the 1991 Act of the UPOV Convention but is a basic requirement in all cases);
- b. be sufficiently consistent and repeatable in a particular environment;
- c. exhibit sufficient variation between varieties to be able to establish distinctness;
- d. be capable of precise definition and recognition
(this requirement is specified in Article 6 of the 1961/72 and 1978 Acts of the UPOV Convention, but is a basic requirement in all cases);
- e. allow uniformity requirements to be fulfilled;
- f. allow stability requirements to be fulfilled, meaning that it produces consistent and repeatable results after repeated propagation or, where appropriate, at the end of each cycle of propagation.

ISF especially draws the attention of the competent national and international authorities on plant variety protection to the scientific rigor, which should govern the definition of the systems for testing DUS characteristics. This is essential to ensure the reproducibility of the results obtained and the consistency of the observations made by different competent authorities on the same characteristic.

ISF also reasserts its total support to the guidelines for conducting DUS testing as published by UPOV after consultation with all the players involved and encourages all present and future UPOV members and others to use those guidelines, in order to harmonize the test results for Breeder's Right.

1.2.1.1.2 Classification of characteristics

ISF proposes the following classification of the characteristics used for DUS testing:

1. UPOV standard phenotypic characteristics which are the characteristics included in the individual guidelines. They are composed of the non-asterisk characteristics, the asterisk characteristics and the grouping characteristics.
2. **Additional phenotypic characteristics**

They must satisfy the general criteria of characteristics set above, have been used by at least one UPOV contracting party and submitted to UPOV.

Those characteristics are consistent with the 1991 UPOV definition of a variety ("*Variety means a plant grouping (...) defined by the expression of the characteristics resulting from a given genotype (...).*"). They are mainly physiological and can be added on the list of characteristics with the agreement of the breeder.

- Yield
- Sugar content
- Pest or Disease resistances
- Herbicide tolerance

This list of additional "phenotypic" characteristics is not exhaustive and subject to changes on a crop-by-crop basis.

3. Additional convincing evidence

In general, these are protein characteristics. They should not be used for populations and synthetic varieties of cross-pollinating species. If used, that should be:

- With the agreement of the applicant,
- Only if all other characteristics failed to establish clear distinctness, despite some evidence of distinctness in UPOV standard characteristics,
- Only if a test procedure has been agreed upon between the competent authority and the applicants.

If used, they can establish distinctness only in combination with phenotypic characteristics, as indicated in categories 1 and 2³

ISF considers that the introduction of new characteristics for DUS testing should be made without creating new obligations on the breeders of the already protected variety. Those breeders should simply be informed by the authority that their varieties have been used in a comparison with new varieties in DUS testing using new characteristics. Only the original official reference sample of the already protected variety could be used for comparison with the "new" variety.

1.2.1.1.3 The case of DNA markers

There is now a tendency in some circles for using DNA markers for facilitating DUS testing. ISF is not opposed to change and plant breeders have always quickly taken the most modern technologies in for their technical work. However, the introduction of new technologies and new concepts must solve more problems than they create and at the moment, ISF considers that DUS testing should continue to be based on phenotypic characteristics. It is preferable as far as possible that D, U and S can be recognized in normal growing conditions. The reasons why ISF is at the moment opposed to the use of DNA markers for DUS testing are as follows:

³ This means that phenotypic characteristics may give two levels of evidence:

- the first level that can be used alone
- the second level needing additional evidence given by non phenotypic characteristics

- DNA marker profiles are not yet predictive of most phenotypic characteristics due to a lack of genetic linkage information or to the relatively complex genetic control of many phenotypic traits.
- If DNA markers were to be used for Distinctness, they would also have to be used for Uniformity and Stability. That would raise practical problems for both technical and financial reasons.
- If DNA markers were to be used for distinctness, then the level of uniformity could not reflect existing levels of variability in varieties which have satisfied current DUS standards. This would avoid narrowing genetic diversity and adding requirements that are only superficial and cosmetic.
- The risk of decreasing the minimum distance to an extreme using DNA markers would be enormous, thus jeopardizing the Breeder's Right.

ISF supports BMT (UPOV Working Party on Biochemical and Molecular Techniques) continuing work on the possible use of biochemical and molecular markers for DUS testing. In particular, it should address the following issues:

- Definition of minimum distances for distinctness;
- Impact on the concepts of uniformity and stability and assessment of those criteria;
- Practical difference between the concepts of distinctness and essential derivation when both of them are assessed using molecular markers.

Until clear answers are given to the questions raised by those issues with a study on impact on Breeder's Right and the possible need of a transitional period, ISF considers that the use of DNA markers for DUS testing could decrease the scope of protection when the goal, in fact, should be to strengthen protection. So the use of these markers for the purpose of DUS testing should be avoided. However, ISF agrees that DNA molecular markers can be used to identify previously described varieties.

For ISF, the use of DNA markers can only be acceptable if it does not impair the scope of protection of plant varieties.

1.2.1.1.4 The special case of disease resistance

Today, one of the essential components of genetic progress provided by plant varieties lies in their ability to offer effective resistance to a considerable range of diseases and pests affecting agricultural plants.

As far as the disease resistance characteristics are concerned, ISF supports any initiative making it possible to use them as characteristics of Distinctness in DUS testing, insofar as:

- They generally satisfy the basic conditions mentioned above in paragraph 1.2.1.1.1;
- And, in particular:
 - The resistances should be clearly defined, notably by specifying the Genus, the species, and if need be the pathotype concerned by the resistance. In case of several races, the race should also be defined;
 - Their evaluation should be covered by a standardized method and this should be available through a known publication or once incorporated into the guidelines for testing the species concerned.

- A different resistance level is only admissible as a characteristic enabling distinctness to be decided on if the levels of expression can be clearly established and if the test results are consistent and technically reliable;
- It is extremely likely that a new protected variety differing only by a disease resistance characteristic from an already existing variety would be considered as essentially derived from that already existing variety.

1.2.1.1.5 The special case of "converted" varieties

By "converted" variety, ISF understands a variety which has been obtained from a pre-existing variety by techniques such as gene transfer, multiple back-crossing leading to a "new" variety differing from the pre-existing one only by the newly included characteristic. Such a converted variety should be considered as essentially derived from the initial variety from which it is derived.

- In order to assess distinctness between the "converted" and the pre-existing varieties, ISF considers it necessary to comply with the UPOV principles stating that a variety is "defined by the expression of the characteristics resulting from a given genotype or combination of genotypes". In addition, in accordance with the 1978 and the 1991 Acts of the UPOV Convention, ISF considers that in the distinctness assessment procedure only the inherent nature of the variety counts, without indicating the methods of development.
- Consequently only converted varieties having a clear phenotypic difference can be considered as distinct from the pre-existing variety. If the differentiating characteristic is not included in the list of the UPOV characteristics, that characteristic should be added in the list by the Breeder's Right office as an additional phenotypic characteristic, at the request and/or with the agreement of the breeder. The characteristic fulfils the basic conditions requested by UPOV.
- The following examples illustrate the ISF position:
 - a. A variety and its herbicide tolerant form to a given herbicide should be considered as distinct (assessment of distinctness should include the spray of the herbicide).
 - b. Two "identical" varieties tolerant to the same herbicide but through different mechanisms of tolerance should not be considered as distinct. This does not preclude the protection of the two different mechanisms by patents if the patenting criteria are met.
 - c. A male sterile line should be considered as distinct from its male fertile counterpart.
 - d. Male sterile forms of a variety obtained *via* for instance different cytoplasms should not be considered as distinct.

If the application for Breeder's Right for a converted variety is lodged by the owner of the pre-existing variety or by an authorized licensee of the owner of the pre-existing variety, and if the converted variety differs from a pre-existing variety only by the introduced characteristic, then, a fast-track procedure for assessing distinctness should be possible. If, during the procedure, other differences are discovered in addition to the introduced characteristics, then, the variety should undergo the normal DUS testing procedure.

1.2.1.1.6 Varieties of common knowledge and management of reference collections: promoting a global variety phenotypic description database

One of the difficulties in assessing distinctness is the increasing number of plant varieties protected in countries member of UPOV. ISF believes that in order to overcome that difficulty the use of DNA markers is not the right approach as in fact the limiting factor is not the lack of phenotypic characteristics but the handling of the reference collections. In order to facilitate that handling, ISF considers that:

- In-depth collaboration, both among PVP offices and between PVP offices and breeders should be encouraged.
- The examination reports belong to the breeder who has paid for the examination procedure. On the request of the breeder the examination reports should be sent free of charge but for a reasonable handling fee to other PVP⁴ offices.
- UPOV and other relevant bodies should investigate as soon as possible the feasibility of a worldwide database of phenotypic description of varieties of common knowledge, at least including but not necessarily limited to varieties protected under the UPOV system. This would facilitate distinctness testing. In particular, in countries, where applicable, the database will be used for grouping comparable varieties and the candidate variety for testing. It would also be useful to plant breeders prior to the application for Breeder's Right. The database should only contain the phenotypic characteristics indicated in the UPOV Guidelines. Those characteristics are not confidential business information and must be publicly available.

ISF also considers that basing the preliminary examination on the data submitted by the breeder should also contribute, to a large extent, to facilitate the application of the UPOV Convention to all species.

ISF urges UPOV and other relevant bodies to investigate the feasibility of establishing such a database.

1.2.1.1.7 Clear distinctness

The clear distinctness, in general known as minimum distance, that should exist between two plant varieties so that they are considered distinct according to the UPOV Convention is a difficult question, which creates debate between the concerned parties.

In order to avoid jeopardizing the Breeder's Right, ISF considers that the minimum distance necessary to declare clear distinctness should not be so narrowed as to impair the protection.

Aware of the biological, genetic and physiological specificities of each plant species, ISF recommends a species-by-species approach of this question.

1.2.2 Novelty

The variety shall be deemed to be new if, at the date of filing of the application for a Breeder's Right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety within specific time limits in or outside the territory of filing.

⁴ PVP offices means Plant Variety Protection authorities in charge of granting Breeder's Right.

These conditions should apply for all kinds of varieties, be they sexually or asexually reproduced, pure lines, populations, hybrids of different kinds. Hybrid parental lines as well should be considered as subject to these conditions as are any other plant varieties.

For several reasons, and in particular to receive best effective protection for the most important achievements of plant breeding and for strengthening their rights by the implementation of the concept of essential derivation, plant breeders are most interested in the protection of parental lines.

Some offices are arguing that parental lines of hybrids which have already been produced and/or sold are not novel on the ground that the seed of the hybrid variety represents "the harvested material of the parental lines".

ISF considers that interpretation as not correct:

- Obviously it is not valid for the male parent.
- It is not valid either for the line used as the female parent of the hybrid as, if we plant the product harvested on the female parental line, the progeny will not be the female parental line itself. That means that the interpretation considering that the hybrid variety represents the harvested material of the parental lines is not consistent with the UPOV definition of a variety, considered as a unit with regard to its suitability to be propagated unchanged.

Of course parental lines have to fulfill the normal novelty criteria as do any other varieties: they have not been sold or otherwise disposed of to others, by or with consent of the breeder, for purposes of exploitation of the variety.

1.3 Exception to Breeder's Right

1.3.1 Breeder's exception

Article 15.1 of the UPOV Convention provides for exceptions to the Breeder's Right and in particular for "acts done for the purpose of breeding other varieties" and except in case of essential derivation for commercialization of the new variety (-ies) obtained, known as the Breeder's Exception.

ISF considers that exception as meaning that a plant breeder can use, for further breeding, protected varieties in accordance with the UPOV Convention he has had access to lawfully. This does not mean that access and use of such protected varieties cannot be subject to restrictions under other international and/or national law.

As parental lines are very often not put on the market as such, some protection offices argue that one of the conditions for granting Breeder's Right to that kind of varieties should be the putting at the disposal of third parties, on request, of the seed of the variety.

ISF opposes strongly that interpretation on the following grounds:

- Legally speaking to impose an additional condition for the granting of Breeder's Right would be contrary to the UPOV Convention which states that no further or different conditions than in article 5 of the 1991 Act must be required. The parallel made with "enabling disclosure" in the patent laws is irrelevant, one of the main differences between Breeder's Right and patents being in fact the breeder's exception.
- The objective of the breeder's exception is to give access to PVPed genetic resources that are commercially available allowing their use for further breeding. In the case of hybrids, the genetic variability of the parent lines is available

through the respective hybrids which are on the market. Breeding a distinct hybrid variety from a released hybrid variety needs more time and effort than using straight away a parent line in order to breed another valuable parent line. The latter would obviously be an infringement of the interest of the owner/original breeder of that first parent line, when done by a third party. For that reason the breeder of the first parent line is not obliged to disclose that parent line to other parties, even if it is protected by Breeder's Right.

1.3.2 Farm saved seed

From the start of agriculture farmers have saved seed from their own crops for re-sowing the following year. In fact that practice was normal and indeed is still essential in circumstances where the only seed available to plant a new crop is seed harvested from a prior season on-farm harvest. Seed that is saved by farmers from the growing of cultivars they have selected themselves does not impact the rights of third parties.

Since the end of the 19th Century, but particularly during the 20th Century, scientific plant breeding based on accumulated new genetic knowledge and new technologies has rendered the development of new cultivars much more efficient than in the past leading to the emergence of a new category of people, the professional plant breeders. Those plant breeders have created and are still creating new cultivars used by an increasing number of farmers worldwide. The new cultivars integrating more and more genetic variability, together with improved cultural practices have resulted in a dramatic increase in food and fiber production

The consequence of that necessary evolution is that plant breeding is no longer a by-product of agriculture, but a separate activity as such. That activity was first undertaken by the public sector. However, progressively during the past century the private sector became increasingly involved, investing heavily in time and money for developing pioneering and inventive new products. The only solutions for the private plant breeders to be paid and to get return on their large investments are either to produce and sell the seed of their varieties themselves or to obtain royalties on seed of their varieties produced by others. This is the reason why an International Convention, the UPOV Convention, finally recognized the concept of Breeder's Right in 1961.

In order to evolve step by step the fathers of the Convention proposed to limit the scope of Breeder's Right to the production, for commercial marketing, of the reproductive or vegetative propagating material of the new variety, and for offering for sale or marketing such material. That was an implicit recognition of the so-called "farmer's privilege".

Thirty years later, in 1991, the Convention was reviewed and the reference to "commercial marketing" was cancelled, thus suppressing the "farmer's privilege". However two exceptions to Breeder's Right in this respect were maintained:

- A compulsory exception for acts done privately and for non-commercial purposes, thus covering farm saved seed produced by subsistence farmers.
- An optional exception, within reasonable limits and subject to the safe-guarding of the legitimate interests of the breeder, of the Breeder's Right in order to permit farmers to use for propagating purposes, on their own holding, the product of the harvest which they have obtained by planting, on their own holding, of the protected variety.

So, the Breeder's Right has been introduced progressively and cautiously over the 2nd part of the 20th century, taking into account the evolution of plant breeding, the

agricultural and socio-economic situations of farmers, and the requirements for food production and environmental security for society as a whole.

ISF members consider that a strong and effective intellectual property protection is necessary to ensure an acceptable return on a research investment and to encourage further breeding and research, that will be essential to meet the challenges mankind has to face in the coming years, i.e. feeding an increasing population whilst preserving the planet.

ISF members are strongly against any "farmer's privilege" going beyond the provision of the 1991 Act of the UPOV Convention, i.e. within reasonable limits in terms of acreage, quantity of seed and species concerned and subject to the safeguarding of the legitimate interest of the breeders in terms of payment of a remuneration and information. The recommendation adopted by the Diplomatic Conference of 1991, indicating that the optional exception "should not be read so as to be intended to open the possibility of extending the practice commonly called "farmer's privilege" to sectors of agricultural or horticultural production in which such a privilege is not a common practice on the territory of the contracted party concerned" must also be taken into account.

Finally ISF members consider that any national legislation authorizing farm saved seed without reasonable limit and without safeguarding the legitimate interest of the breeders is not in conformity with the 1991 Act of the UPOV convention. In addition it would not be an effective *sui generis* system in the meaning of the article 27.3.b of the TRIP's agreement.

1.4 Essential Derivation

1.4.1 Definition of essential derivation

Article 14.5(b) of the 1991 Act of the UPOV Convention states that a variety shall be deemed to be essentially derived from another variety, the initial variety, when

- i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;
- ii) it is clearly distinguishable from the initial variety and;
- iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Essentially derived varieties may be obtained, for example, by selection of natural or induced mutants, by selection of a somaclonal variant, by selection of variant individual plants in the initial variety, by backcrossing or transformation by genetic engineering.

1.4.2 ISF consideration on essential derivation

ISF strongly supports this concept of essentially derived varieties (e.d.v.) which allows the new technological developments to be taken into account. It has also the potential to drastically decrease the risk of plagiarism in plant breeding. ISF also considers that this principle, whilst appropriately strengthening Breeder's Right, does not restrict the breeder's exception, a key feature of the UPOV Convention.

ISF notes that even if there are not yet international agreed-upon professional rules and usages for assessing essential derivation and for solving disputes, the concept

has already greatly contributed to avoid infringement, breeders being more careful in their breeding programs.

As will be shown in the following, this principle mainly involves questions of scope of protection and enforcement of the rights of the breeder. It is, therefore, left to the initiative of the breeder to enforce these rights. ISF stresses that the determination of essential derivation is not part of the procedure of the granting of the Breeder's Right. However, registration data of the varieties based on UPOV guidelines should be available after granting of rights.

1.4.3 ISF interpretation of article 14.5 of the 1991 Act of the UPOV Convention

i) The technical aspect

For a variety to be considered as essentially derived, it must fulfill three requirements in relation to the initial variety while retaining the expression of the essential characteristics of the initial variety:

- clear distinctness in the sense of the UPOV Convention;
- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;
- predominant derivation from an initial variety.

If one of these requirements is not fulfilled, there is no essential derivation.

ii) The legal aspect

The principle of dependence only exists in favor of a non essentially derived protected variety. This means that:

- the initial variety must be a protected one;
- dependence can only exist from one protected variety alone;
- an essentially derived variety can be directly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety. It is possible to have a "cascade" of derivation. However, each essentially derived variety shall only be dependent on one, the protected initial variety. A cascade of dependence shall not exist, the principle having been introduced to better protect the breeder of the initial variety and not those having made derivations from his work.

Essential derivation is a matter of fact whereas dependency resulting therefrom is a possible legal consequence. Therefore, if an e.d.v. has been claimed and proved as such with legal validity, it remains an e.d.v. forever. Even if the protection period of the i.v. has been exhausted, a variety derived from the first variety in a chain of essentially derived varieties remains an e.d.v. and the remaining varieties in the chain will still be essentially derived from the i.v., but not dependent of that no longer protected variety. The reason for this lies in the spirit of the concept of dependency. This principle has mainly been introduced to protect more efficiently the initial breeder and not those who make derivations from his work.

1.4.4 Assessment of essential derivation

The assessment of essential derivation takes place after establishing that a variety is clearly distinguishable from all varieties which are a matter of common knowledge and should consider the following requirements:

- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or the combination of genotypes of the initial variety;
- predominant derivation from the initial variety.

The first requirement could be based on reliable phenotypic characteristics: either close relationship in general which could lead to a "conformity threshold" parallel to the minimum distance threshold used for distinctness or only small differences in some simply inherited characteristics. If this requirement is considered as fulfilled, then, we have to assess the second one, which is "predominant derivation from the initial variety".

Predominant derivation from the initial variety, implies that the initial variety or products essentially derived therefrom have been used in the breeding process.

In order to prove that use, various criteria or a combination thereof may be used:

- combining ability
- phenotypic characteristics
- molecular characteristics
- breeding records.

1.4.5 Burden of Proof

According to the general rule of burden of proof, it is to the owner of the initial variety to prove essential derivation and then claim dependency. However if the owner of the i.v. can give reasonable evidence of essential derivation (*prima facie* proof), ISF is in favor of the reversal of the burden of proof. For *prima facie* proof, the following elements should be sufficient:

- strong phenotypic similarity;
- only small differences in some simply inherited characteristics;
- strong genetic similarity.

If the owner of the i.v. has fulfilled one of the above requirements, then the second breeder would have to prove that there is no predominant derivation, or that he had not used the i.v., or a variety essentially derived from that i.v..

The use of distance coefficients to define a threshold which would be a trigger point for the reversal of the burden of proof is another interesting approach. Up to now, ISF has mainly worked on thresholds based on distances measured by molecular markers. Geneticists and statisticians consider that technically it is equally possible to measure distance coefficients using morphological markers but that these distances are not always reflective of genetic distances or of pedigree relationships. Additionally, use of morphological characteristics would probably be more difficult due to environmental factors, and much more expensive.

The threshold would divide the scale of conformity into two parts: below the threshold there would be no presumption of essential derivation, above the threshold there would be presumption of essential derivation and the burden of proof of non predominant derivation would fall on the breeder of the putative e.d.v.

The threshold will certainly vary from species to species, depending on the existing genetic variability within the species and the established breeding procedures⁵.

⁵ ISF sections/members are working on the definition of a possible threshold for various species, in order to put this legal concept into practice. Studies have been carried out on tomato, rye grass, maize, and results have been published. Studies are going on on lettuce and oilseed rape.

ISF recommends to its members, in any case of dispute, to first enter into a conciliation or arbitration procedure according to ISF Conciliation and Arbitration Procedure Rules before resorting to legal action.

1.4.6 Entry into force

After careful consideration of the economic, legal and technical aspects involved, the following is concluded:

In the case of implementation of the 1991 Convention (see chapter IX of the 1991 revised text of the UPOV Convention), the national laws should include the following:

- i) All existing Breeder's Right before implementation should be regarded as independent and should enjoy all the rights given by the revised Convention.
- ii) Nevertheless, only where such a protected plant variety is not itself an essentially derived variety (e.d.v.) should the holder enjoy the rights under article 14, par. 5 of the revised Convention.
- iii) All e.d.v. for which an application for Breeder's Right has been filed or acts mentioned in article 14, par. 1 of the revised Convention have been done first on or after the implementation date should be subject to the new concept of e.d. and dependency.
- iv) The date of filing an application for Breeder's Right should be decisive and not the date of granting Breeder's Right.
- v) There should be no difference between the date of application and acts with the plant variety because at the date of application it can be imputed that acts have already been done with this variety (e.g. production of propagating material).

1.5 Distinctness and Essential Derivation

The finally adopted definition of essentially derived varieties during the Diplomatic Conference of March 1991 is such that it could be possible to confuse the concepts of distinctness and essential derivation. This possibility would be increased if DNA markers were to be used to determine distinctness or if they were used prematurely without prior studies to help determine edv status. The risk would be to have first overlap and then confusion of the two notions.

As it is clear that the two concepts are legally different, ISF considers that it would be a mistake to confuse them for the following reasons:

- the assessment of distinctness is based on clear difference between expressed characteristics;
- the assessment of essential derivation is based on conformity of the essential characteristics resulting from the genome;
- the question of distinctness is a question of granting the right whereas the question of essential derivation is a question of the scope of protection.

In addition some maize breeders are working on a contractual solution for implementation of the e.d.v. concept by defining a free "green" zone without dependency, a "red" zone with automatic dependency and an "orange" zone in between where a possible dispute should preferably be settled through arbitration. Such "agreement", which balances the interest of a free "green" zone with a systematic dependency "red" one, will be binding only on the signatories.

Furthermore, the decision of distinctness and then of granting the property title (if the variety is also new, uniform and stable) is the responsibility of official services, whereas the demonstration of essential derivation is the business of the holder of the right of the presumed initial variety.

For these reasons, ISF considers that:

- there are good grounds to maintain separately the two notions of distinctness and essential derivation;
- for these reasons, it is necessary as far as possible to use different tools for defining the two concepts, using phenotypical characteristics for DUS testing;
- assessment of essential derivation could be based on variety origin, breeding methods, heterosis, appropriate phenotypic and/or genotypic characteristics.

1.6 Goals of ISF

ISF is committed to take actions to strengthen the 1991 Act of the UPOV Convention by striving for:

- A strict interpretation of the Exceptions to the Breeder's Right;
- A strong, practical and enforceable e.d.v. system;
- A better protection of parental lines that have not been sold, exploited or otherwise disposed of;
- Ratification of the UPOV 1991 Act by all UPOV members.

2. Legal protection of biotechnological inventions

For biotechnological inventions, ISF considers that the most appropriate protection is through patents, provided, of course, that the patentability criteria, namely novelty, industrial application and non-obviousness, are fulfilled.

The patent system should provide strong and enforceable protection of claims that are a fair balance between enabling disclosure and prior art. Protection by patent of a biotechnological invention should not be exhausted when that biotechnological invention, inserted in a plant variety is used by others.

Novel plant breeding procedures or genetic engineering methodologies in which the procedures or methodologies are decisive for achieving an inventive result should be eligible for patent protection.

ISF notes that many of the issues that have been raised with respect to the legal protection of biotechnological inventions by patents have been solved by legislation, examination guidelines, decisions by Courts and Opposition Boards. While these developments are not global and only partly implemented, ISF notes with satisfaction the following positive signals:

- Sequences or partial sequences of genes are subject to the same criteria of patentability as in all other areas of technology (novelty, inventive step and industrial application) such that the industrial application (utility) must be disclosed in the patent application as filed.
- In other words, it is accepted that a mere DNA sequence or nucleotide without indication of a function does not contain any technical information and is not a patentable invention
- It is accepted that a utility must be specific to the subject matter claimed, that it must be credible for a person of ordinary skill and be practical, meaning attributing a real world value to the claimed invention

- Biological material that is isolated from its natural environment or produced by means of a technical process may be patentable even if it previously occurred in nature;
- Protection conferred by a patent on a biological material possessing specific characteristics extends to biological material obtained through propagation or multiplication if possessing the same characteristics
- Protection for a process that enables biological material to be produced and which possesses specific characteristics extends to biological material directly obtained through that process and to its progeny.

ISF is however convinced that there is substantial room for improvement in terms of speed and quality of patent examination, opposition and litigation procedures and is concerned that the costs involved in these procedures are often detrimental to the quality and enforceability of patents in general. ISF therefore urges governments to give the necessary means in terms of human resources and skills to the patent offices and courts. ISF is also in favor of complete transparency at all steps of the patent examination by giving to anybody a full and instant access to the examination file.

3. The Coexistence of Breeder's Right and Patents

As already indicated in this document, ISF considers that Breeder's Right (and patent for plant varieties where allowed by law) and patent protection for biotechnological inventions, are efficient protection systems. It is thus necessary to define a fair coexistence of the two rights.

The introduction of the concepts of essential derivation and dependency in the 1991 Act of the UPOV Convention is a welcome initiative to bridge the two systems, in the interest of all the actors involved.

However further clarification is needed as regards the use of transgenic varieties containing patented elements and protected by Breeder's Right for further breeding. ISF is strongly attached to the breeder's exception provided for in the UPOV Convention and is concerned that the extension of the protection of a gene sequence to the relevant plant variety itself could extinguish this exception.

Therefore ISF considers that a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, if the new developed variety is an e.d.v. or if it is inside the scope of the patent's claims, a consent from the owner of the initial variety or of the patent must be obtained.

ISF is not generally in favor of compulsory licensing. Unrestricted compulsory licensing would make meaningless the new concept of dependency as well as the protection by patent on "biotechnological inventions". ISF acknowledges the principle of compulsory licensing in case of public interest as provided for in patent laws. ISF has also considered the concept of compulsory licensing in case of "significant technical progress of considerable economic interest", as provided for in the European Directive for the protection of biotechnological inventions and which is in line with the provision of the TRIP's agreement. However, the implementation of such a clause would have to be left to courts and thus be time-consuming and expensive. ISF considers that in any case, the best solution is to encourage contractual voluntary licensing for both essentially derived varieties and patented traits.