

Protection of Biotechnological Inventions and Plant Breeding

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Protection of Biotechnological
Inventions and Plant Breeding

Summary

Introduction: Background on intellectual property rights

1. Protection of biotechnological inventions
2. Plant variety rights

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Introduction

- Research and innovation take place in every field of technology, including living organisms
- Research in this field also requires intellectual property protection
- Intellectual property raises specific issues when applied to living organisms

Different families of IP rights

- Protection of distinctive signs (trademarks, geographical indications)
- Protection of literary and esthetical creations (copyright, industrial designs)
- Protection of technical creations (patents, plant variety rights, trade secrets, etc.)

Rationale for the protection of technical creations

- Twofold purpose of IP rights:
 - ▶ a right of property on any creation (a human right)
 - ▶ reward for the progress of science resulting from the contribution to increase scientific knowledge
- As a result of this rationale:
 - ▶ known product or process cannot be protected
 - ▶ only the new and inventive product or process can be protected
 - ▶ protection granted cannot extend to known product or process

Object of the protection on technical creations

- The protection can relate to:
 - ▶ products (product claims or device claims)
 - ▶ process (process claims or use claims)

Invention regarding molecular technology and living organisms

- Product claim, *e.g.*:
 - ▶ Isolated DNA sequence, antibody, protein, etc.
 - ▶ GMO
 - ▶ New plant variety or new animal variety
- Process claim, *e.g.*:
 - ▶ Biotechnological process
 - ▶ Process to obtain a GMO
 - ▶ Plant or animal breeding method
 - ▶ Method for the detection of DNA (diagnosis)
- Device claim, *e.g.* device to perform a process
- Use claim, *e.g.* use of DNA for the treatment of diseases

Issues raised by the protection of biotechnological invention and living organisms

- Can “anything under the sun” be patented?
- Are ordinary conditions of patentability applicable?
 - ▶ invention v. discovery
 - ▶ novelty requirements (DNA fragments or antibodies exist in the nature)
- Is the protection conferred by a patent appropriate to living organisms?

Protection of Biotechnological Inventions and Plant Breeding

1. Protection of biotechnological inventions

- 1.1. Patentability conditions
- 1.2. Scope of protection

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Protection of Biotechnological Inventions and Plant Breeding

Applicable provisions

- Munich Convention on the grant of European patent, 5 October 1973
- **Directive 98/44/EC of 6 July 1998, on the legal protection of biotechnological inventions**
 - ▶ Directive 98/44 is now ten years old and the Commission would have to evaluate its effects
- National patent laws (implementing Directive 98/44/EC)

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1.1. Patentability conditions

- Negative conditions:
 - ▶ Non patentability of inventions contrary to public order or morality
 - ▶ Non patentability of plant and animal varieties
 - ▶ Non patentability of essentially biological processes
- Positive conditions:
 - ▶ Invention v. discovery
 - ▶ Novelty
 - ▶ Inventive step
 - ▶ Industrial application
 - ▶ Sufficient description (enablement)

Non patentability of inventions contrary to public order or morality

- The general rule (Art. 53 EPC):

"European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States";
- Art. 6 of Directive 98/44 provides that:

"1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

 - (a) processes for cloning human beings;*
 - (b) processes for modifying the germ line genetic identity of human beings;*
 - (c) uses of human embryos for industrial or commercial purposes;*
 - (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

Non patentability of inventions contrary to public order or morality

- Special treatment for the human body (Art. 5 of Directive 98/44):
 - ▶ Not patentable: *"The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."*
 - ▶ Patentable: *"An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."*

Non patentability of inventions contrary to public order or morality

- No European definition of morality
 - ▶ "ordre public" covers the protection of public security and physical integrity of individuals as part of society
 - ▶ "Morality" pertains to conventionally-accepted standards of conduct in the European culture

Case law on public order or morality

- Harvard college Onco-mouse decision, EPO Opposition Division, 3 April 1992, concerning patentability of genetically modified animals: it is necessary to compare the sufferings inflicted on the animal with the advantages drawn therefrom
- Relaxine decision, EPO Opposition Division, 8 December 1994, regarding DNA coding for human protein: as an exception to patentability, such provision must be restrictively interpreted and only concerns inventions regarding biological material in its natural environment
- *Greenpeace v. Plant Genetic Systems*, EPO Board of Appeal, 21 February 1995: none of the claims of the patent in suit refers to subject-matter which relates to a misuse or destructive use of plant biotechnological techniques; since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability may not be based on the so-called "balancing exercise" of benefits and disadvantages, as submitted by the appellants. The board observes that such a "balancing exercise" is not the only way of assessing patentability but just one possible way, perhaps useful in situations in which an actual damage and/or disadvantage (e.g. suffering of animals) exists

Case law on public order and morality (cont'd: Stem cell is a big issue)

- University of Edinburgh, EPC Opposition Divisions, 21 July 2003:
- Warf (Wisconsin Alumni Research Foundation):
 - ▶ Claim: A cell culture comprising primate embryonic stem cells....: refused by the Examining Division (June 2004)
 - ▶ T1374/04, 18 November 2005, G2/06, EPO Enlarged Board of Appeal: patentability of human embryonic stem cells. Decision expected soon!
- Brüstle patent, granted in limited form, January 2006:
 - ▶ Claim 1: Non-tumorigenic cell composition obtained from mammalian embryonic stem cells, obtainable by the steps of (a) proliferation of ES cells, (...) with the proviso that the method does not include the destruction of human embryos

Opinion of the European Group on Ethics in Science and New Technologies (EGE)

- Opinion No. 16 of 16 May 2002: **Ethical aspects of patenting inventions involving human stem cells**
- EGE 16:
 - ▶ **Unmodified stem cells** are **too close to the human body**; their patenting may be considered as a form of commercialisation of the human body; would also lead to *"too broad patents"*
 - ▶ Only **stem cell lines** which have been **modified** by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application may be patentable
 - ▶ *"As to the patentability of **processes** involving human stem cells, whatever their source, there is **no specific ethical obstacle**, in so far as they fulfil the requirements of patentability"*

Non patentability of plant and animal varieties

- Plant and animal varieties shall not be patentable (Art. 4 of Directive 98/44 and Art. 53 b) EPC)
- 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
 - ▶ inventions which concern a microbiological or other technical process or a product obtained by means of such a process shall be patentable

Case law on plant varieties

- Harvard college Onco-mouse decisions, EPO Board of Appeal, 3 October 1990 and 3 April 1992:
 - ▶ The exception to patentability applies to certain categories of animals (varieties) but not to animals as such
 - ▶ Mammals and rodents constitute a taxonomic classification unit higher than "animal variety", and are therefore not excluded under this provision from patentability
- *Greenpeace v. Plant Genetic Systems*, EPO Board of Appeal, 21 February 1995:
 - ▶ The concept of "plant varieties" refers to any plant grouping within a single botanical taxon of the lowest-known rank which is characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics
- *Transgenic plant v. Novartis*, EPO Enlarged Board of Appeal G1/98 of 20 December 1999:
 - ▶ A genetically modified plant containing DNA coding for a given protein can be patented because not limited to a variety

Non patentability of essentially biological processes

- Essentially biological processes for the production of plants or animals shall NOT be patentable (Art. 53 b) EPC, Art. 4.1 of Directive 98/44)
 - ▶ "A process for the production of plants or animals is essentially biological if it consists **entirely** of natural phenomena such as crossing or selection" (Art. 2.2 of Directive 98/44)
- Microbiological processes are patentable

Case law regarding essentially biological processes

- *Greenpeace v. Plant Genetic System*, EPO Board of Appeal, 21 February 1995: if the technical step is essential in the result, the process is not essentially biological
- *Transgenic plant v. Novartis*, EPO Enlarged Board of Appeal G0001/98 of 20 December 1999
- T83/05 of 3 March 2007, T1242/06 of 22 May 2007: the Enlarged Board of Appeal (G2/07 and G1/08) has been asked to rule on patentability of a process for the production of plants which includes both crossing/selecting and technical steps

Novelty requirement

- Article 54 EPC sets the novelty requirement:

“(1) An invention shall be considered to be new if it does not form part of the state of the art.

“(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.”

Novelty requirement (cont'd)

- Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature (Art. 3.2 of Directive 98/44)
- An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element (Art. 5.2 of Directive 98/44)

Case law regarding novelty

- Genentech, EPO Board of Appeal, 20 July 1993: natural substance is not prior art because not directly available as it needs to be isolated and purified
- Relaxine, EPO Division of Opposition, 8 December 1994: isolated or cloned DNA is novel

Industrial application

- An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture (Article 57 EPC)
- Industrial application can result notably from use in agriculture
- This condition is an issue for biotechnologies when the invention covers DNA or proteins with unknown function

Industrial application (cont'd)

- In order to comply with the industrial application criterion, it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs (Recital 24 of Directive 98/44)
- The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application (Art. 5.3 of Directive 98/44)

Case law of industrial application

- UK Patent Court, *Eli Lilly v. Human Genome Sciences*, 31 July 2008

Sufficient description

- The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 83 EPC)
- Recital 13 and Art. 13 of Directive 98/44 provide a deposit mechanism in addition to written descriptions when an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art
- Failing that, the description shall be considered inadequate for the purposes of patent law

1.2. Scope of patent protection and exceptions

- 1.2.1. Applicable provisions
- 1.2.2. Scope of patent protection
- 1.2.3. Exceptions to patent protection

1.2.1. Applicable provisions

- Articles 8 to 11 of Directive 98/44/EC on the protection of biological inventions
- National provisions, *e.g.* Articles L. 613-2-2 and L. 613-2-3 of the French Intellectual Property Code

1.2.2. Scope of protection (product claims) Article 8 of Directive 98/44

- The protection conferred by a **patent on a biological material** possessing specific characteristics shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics
- The protection conferred by a **patent on a product containing or consisting of genetic information** shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function

Scope of protection

- The protection conferred by a claim on a gene extends to, *e.g.*:
 - ▶ cells containing that gene
 - ▶ plants containing that gene
 - ▶ plants obtained by reproduction or multiplication of that plant
 - ▶ plant obtained by crossing with that plant provided the gene is contained and performs its functions in the new variety
 - ▶ harvested material of that plant (except if the patented product was sold for the purpose of producing harvest)

Scope of protection (process claims) Article 9 of Directive 98/44

- The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to:
 - ▶ biological material directly obtained through that process and
 - ▶ to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics

Improper implementation of Art. 9 of Directive 98/44 in France

- *"The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description"*
(Art. L. 613-2-1 French IPC)
- This provision introduces a limitation to the scope of product claims which does not seem to correspond to Art. 9 of Directive 98/44

Case law on scope of protection

- District Court of The Hague, *Monsanto v. Cefetra*, 19 March 2008 (interim judgement): question of interpretation of Art. 9 of Directive 98/44 submitted to ECJ
- UK Patent Court, *Monsanto v. Cargill International*, 10 October 2007

1.2.3. Limits and exception to patent protection

- 1.2.3.1. The normal use of biological material sold by the right-holder or with his consent
- 1.2.3.2. Breeder's or research exemption
- 1.2.3.3. Farmer's exemption (for given species)

1.2.3.1. Normal use of biological material

- The protection shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication (Art. 10 Directive 98/44)

1.2.3.2. Breeder's or research exemption

- The rights afforded by the patent shall not extend to:
 - ▶ acts done for experimental purposes relating to the subject-matter of the patented invention (Article L. 613-5 b French IPC)
 - ▶ acts intended to discover or develop new varieties (Article L. 613-5-3 French IPC)
- Provisions in national law only, not in Directive 98/44

Breeder's or research exemption (cont'd)

- Breeding is explicitly covered by the specific provisions of the breeder's exemption
- But it is not clear whether breeding is covered by the general experimental purpose exemption

Breeder's or research exemption (cont'd)

- The exemption only covers the act of breeding or research, not the exploitation of the breeding result
- If new bred variety still contains the patented genetic material, it is still covered by the patent (similar to EDV)

1.2.3.3. Farmer's exemption

- The sale or other form of commercialisation of plant propagating material to a farmer by the patent holder or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest, for propagation or multiplication by him on his own farm (Article 11 of Directive 98/44, Art. L.613-5-1 French IPC)
- The extent and conditions of this derogation correspond to those under Article 14 of Regulation (EC) No. 2100/94.
 - ▶ ECJ, 14 October 2004, *Saagut v. Brangewitz*
The right-holder cannot ask companies whether they used farm saved seeds; information may be requested only on the extent of the use, when the right-holder knows that farm saved seeds had been used

2. Plant breeder's rights

- 2.1. Reasons for plant breeders' rights
- 2.2. Application provisions
- 2.3. The object of the Community plant variety right
- 2.4. The grant procedure of the exclusive right
- 2.5. The scope and limits of the exclusive right

2.1. Reasons for plant breeders' rights

- Patent law is inappropriate
 - ▶ discoveries are not patentable
 - ▶ the requirement of inventive step is inappropriate
 - ▶ novelty is difficult to preserve in field cultivation
 - ▶ description is often insufficient to reproduce the plant variety

2.2. Applicable provisions

- 2.2.1. UPOV Convention
- 2.2.2. National provisions, *e.g.* France
- 2.2.3. Community plant variety right

2.2.1. The UPOV Convention

- International Convention for the Protection of New Varieties of Plants, signed in Paris on 2 December 1961
- 66 Contracting Parties (29/10/2008)
- Called "UPOV Convention" because it creates a union for the protection of new varieties of plants between the Contracting Parties
- Convention amended three times
 - Additional Act of 10 November 1972
 - Revision of 23 October 1978
 - Revision of 19 March 1991 (second generation)
- The UPOV's mission is *"to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society"*.

The UPOV Convention

- Recognition of the plant breeder's rights
- The subject of protection is a new, distinct, uniform and stable plant variety of natural or artificial origin
- The plant variety should be identified by a non-misleading variety denomination that becomes the generic designation of the variety
- The protection should confer exclusive rights regarding the marketing of the variety reproduction or multiplication material but the use for improvement purposes should be free
- The Contracting Parties may provide a *sui generis* system of protection or a patent
- The breeder's right is independent of the regulation regarding the production and marketing of seeds

Revision of 19 March 1991

- Deep transformation of the spirit and balance of the Convention
- Four significant amendments:
 - ▶ possible legalisation of **farm seeds**
 - ▶ introduction of the notion of “**essentially derived variety**”
 - ▶ **extension** of the protection
 - ▶ **removal** of the prohibition of combining protections

2.2.2. National protection, e.g. France

- Plant variety right (*certificat d'obtention végétale, COV*) created by French Law of 11 June 1970 and now governed by Articles L. 623-1 to L. 623-35; R. 623-1 to R. 623-58 of the French Intellectual Property Code
- Right granted by the *Comité de la protection des obtentions végétales* (CPOV - Paris – Ministry of Agriculture)
- Grants a protection on the French territory only
- First generation text in accordance with the UPOV Convention of 1978
- Bill passed by the *Sénat*, submitted to the *Assemblée Nationale* on 2 February 2006, to have French legislation complied with the UPOV Convention of 1991 (still in process)

2.2.3. Community plant variety right

- Council Regulation (EC) No. 2100/94 of 27 July 1994, establishing a Community system of protection for plant varieties
- Second generation text in accordance with the UPOV Convention of 1991
- Instauration of Community law that coexists with the national laws
- Interdiction of combining both Community and national protections for a same plant variety
- Community Plant Variety Office (CPVO) in Angers, France

Common principles of protection of plant innovation

- The aim is to reward the breeder and to grant it an exclusive right of exploitation in consideration of its contribution to the progress in the art and disclosure of its variety for new innovations
- For that purpose, the breeder is granted a property right over its technical creation
- The object of protection is the result of the breeder's work: the variety (the process is not protected)
- The conditions of protection are adjusted to the plant field, *i.e.*, distinctness, uniformity, stability and novelty
- The variety should be designated by a plant denomination

2.3. The object of the Community plant variety right

- 2.3.1. The Community plant variety right protects a plant variety
- 2.3.2. To be protectable, the variety should exhibit some characteristics: distinctness, uniformity, stability, novelty
- 2.3.3. The Community plant variety right also protects the plant variety denomination

2.3.1. The notion of plant variety

- A plant variety is:
 - ▶ a plant grouping
 - ▶ within a botanical taxon of the lowest known rank
 - ▶ that can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes
 - ▶ distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
 - ▶ considered as a unit with regard to its suitability for being propagated unchanged

Explanation of the botanical taxon

- The large **plant kingdom** has been hierarchically classified (taxonomy) according to a classification system containing numerous divisions and subdivisions, which are so many "taxa"

- Plant kingdom
- Division
- Class
- Order
- Family
- Genus
- Specie
- Variety

High

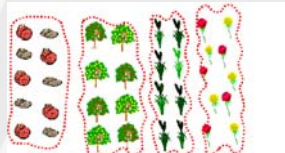
Low

Explanation of the botanical taxon

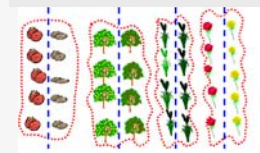
Plant kingdom



Species



Varieties



The species concerned by the Community plant variety right

- Art. 5 Regulation: “Varieties of all botanical genera and species”
- Doubts:
 - ▶ algae
 - ▶ fungus
 - ▶ plant micro-organisms (yeast, some algae and some microscopic fungus)

2.3.2. The characteristics of the protectable variety

- ▶ distinctness (2.3.2.1.)
- ▶ uniformity (2.3.2.2.)
- ▶ stability (2.3.2.3.)
- ▶ novelty (2.3.2.4.)

2.3.2.1. Distinctness

- Regulation (EC) No. 2100/94, Art. 7
- A variety is "*distinct if it is **clearly** distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application*".

2.3.2.2. Uniformity

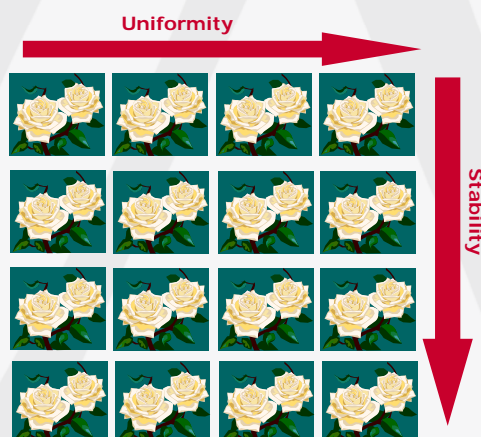
- Regulation (EC) No. 2100/94, Art. 8
- A variety is "*uniform if, **subject to** the variation that may be expected from the particular features of its propagation, it is **sufficiently** uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description*".

2.3.2.3. Stability

- Regulation (EC) No. 2100/94, Art. 9
- A variety is “stable is the **expression of the characteristics** which are included in the examination for distinctness as well as any others used for the variety description, **remain unchanged after repeated propagation** or, in the case of a particular cycle of propagation, at the end of each such cycle”.

Uniformity and stability

- 1st generation
- 2nd generation
- 3rd generation
- 4th generation



2.3.2.4. The criterion of novelty

- Definition of the novelty
- Novelty-destroying acts
 - ▶ disclosure (loss of novelty owing to the breeder itself)
 - ▶ anticipation (loss of novelty owing to others)

Definition of novelty

- Art. 10 of the Regulation
 - ▶ A variety is new if variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with the consent of the breeder.
 - ▶ Absolute novelty in space and time (subject to the grace periods)

Disclosure

- Art. 10 §1 of the Regulation (EC) No. 2100/94
- Disclosure is found when the variety constituents or harvested material have been:
 - ▶ sold or "otherwise disposed of" (marketed)
 - ▶ to others, **by or with the consent of the breeder, for purposes of exploitation of the variety**
 - ▶ earlier than one year before the date of application, within the territory of the Community
 - ▶ earlier than four years or, in the case of trees or of vines, earlier than six years before the date of application

2.3.3. The variety denomination - Plan

- *Raison d'être* of the variety denomination
- Texts relating to the variety denomination
- Selection of the variety denomination
- Status of the variety denomination

Raison d'être of the variety denomination

- The variety denomination was sometimes used as a means for protecting creations in the absence of *sui generis* law
- The variety denomination is compulsory not only for protecting innovation but also for statutory reasons regarding the plant marketing
- A special condition: it is the only condition of protection that does not relate to the characteristics of the plant variety or the acts concerning the same

Selection of the variety denomination

- It is up to the holder to choose the variety denomination that should (Art. 63 §3 Regulation):
 - (1) be possible (not contrary to public order or not likely to give offence)
 - (2) allow identification without confusion or ambiguity (distinctive and not deceptive)
 - (3) be easy to recognize and reproduce by its users
 - (4) be uniform, as much as possible; and
 - (5) be available.

Availability of the variety denomination

- The variety denomination should not violate the third parties' prior rights (patronymic name, copyright, designation of origin, trademark ...)
- If a third party holds a trademark over the sign used as a denomination:
 - ▶ It can lodge a written objection to the grant of the Community plant variety right
 - ▶ If it has been made aware of it after the grant of the Community plant variety right, it can assert its prior right to hamper the free use of the variety denomination (Art. 18(2) Regulation)
- The variety denomination cannot be an usual or reserved sign (Art. 63(3)d Regulation)

Effect of the selection of the variety denomination

- The denomination becomes the generic name of the variety (Art. 13-7 UPOV and Art. 17 Regulation)
- Its use will be:
 - ▶ obligatory for any commercial transaction relating to the variety's constituents
 - ▶ facultative, unless otherwise provided for in law, for any transaction relating to any other material of the variety
- This obligation remains even after the termination of the Community plant variety right

Status of the variety denomination

- Failure to use the variety denomination of a Community plant variety right is an act of infringement


2.4. The grant procedure

- 2.4.1. The application
- 2.4.2. The examination
- 2.4.3. The grant of the right
- 2.4.4. The sanctions for non-compliance of the requirements of grant (cancellation and nullity)

2.4.1. The application

- The applicant
 - ▶ personal right to the breeder (person who bred, or discovered and developed the variety) or his successor in title; joint right if the variety was bred in team or in application of a written declaration
 - ▶ if the breeder is an employee, the right belongs to the person designated by the national law applicable to the employment relationship
 - ▶ the applicant should be a national of a Member State of the European Union or of the UPOV, be domiciled or have his seat or an establishment in one of these States. The Commission can extend the access to persons who do not meet these requirements if there is reciprocity with their State

The application

- The filing of the application
 - ▶ with the CPVO in Angers, France 
 - ▶ with one of the sub-offices or national agencies entrusted by the Community Office
 - ▶ by a representative being domiciled or having a seat or establishment on the territory of the European Union
 - ▶ physically or by mail

The application

- The content of the application (1):
 - ▶ application for Community plant variety right
 - ▶ identification of the botanical taxon
 - ▶ identification of the applicant or, if so the case, the joint applicants
 - ▶ the breeder's name and the guarantee that no other person took part in the breeding; if the applicant is not the breeder, the document proving the assignment of the rights
 - ▶ a proposal for a variety denomination

The application

- The content of the application (2):
 - ▶ a technical description of the variety
 - ▶ the geographical origin of the variety
 - ▶ the power of the representative(s)
 - ▶ precisions regarding any prior commercialisation of the variety
 - ▶ precisions regarding any other application filed for the variety
 - ▶ the proposal for a variety denomination

2.4.2. The examination

- Examination performed by the CPVO
 - ▶ Formal examination of the application
 - ▶ Substantive examination
 - ▶ the plant meets the definition of a plant variety (Art. 5)
 - ▶ the variety is new
 - ▶ the applicant is entitled to file an application
 - ▶ the variety denomination proposed by the applicant is suitable

The examination (cont'd)

- Technical examination: the further characteristics of the variety (distinctness, uniformity, stability) are controlled by an **Examination Office** that will send to the CPVO an **examination report** (planting of the variety and analyses)
- In parallel, any person can send to the Office a **written objection**, either because one of the substantive requirements of protection would not be met, or because there would be an impediment to a proposed variety denomination

2.4.3. The grant of the Community plant variety right

- If the Office is of opinion that the findings of the examination are sufficient to decide on the application and there are no impediments, it grants the Community plant variety right
- Its decision includes an official description of the variety
- The grant of the Community plant variety right is entered in the Register and published in the Gazette of the Office
- The Office issues a certificate of a Community plant variety right that proves the grant of this right
- The grant of the right is notified to the applicant and, if necessary, to the parties to the procedure
- This decision however may be appealed before the CPVO Board of Appeal then before the Court of First Instance (then an appeal on points of law only is possible before the ECJ): on 31 January 2008 the Court of First Instance handed down its first decision in an appeal against a decision of the CPVO Board of Appeal (case T-95/06). Another decision was rendered by the Court of First Instance (case T-187/06) on 19 November 2008

2.4.4. The sanctions for non-compliance of the requirements of grant

- 6 grounds for **cancellation** in Community law (Art. 21 Regulation)
 - ▶ Established lack of stability or uniformity
 - ▶ The holder's refusal to provide the CPVO and the examination offices in charge of the technical examination of the variety with all the necessary information to appraise if the variety continues to exist as such
 - ▶ Refusal to submit the material of the variety or to check whether the appropriate steps have been made to ensure that the variety continues to exist as such
 - ▶ Refusal to propose another suitable variety denomination when the initial denomination is not appropriate or is no longer appropriate
 - ▶ Failure to pay such fees to keep the Community right in force
 - ▶ The holder is no longer entitled to be the holder of a Community right

The sanctions for non-compliance of the requirements of grant (cont'd)

- **Nullity** of the Community right (Art. 20)
 - ▶ if the requirements of Articles 7 (distinctness) **or** 10 (novelty) were not met at the time of the grant of the Community right
 - ▶ where the grant of the Community right has been essentially based upon the information and documents furnished by the applicant, if the requirements of Articles 8 (uniformity) **and** 9 (stability) were not met at the time of the Community right
 - ▶ if the right has been granted to a person who is not entitled, unless it is transferred to the person who is entitled

2.5. The scope and limits of the exclusive right

2.5.1. The definition of the exclusive right

2.5.2. The scope of the exclusive right

2.5.3. The limits of the exclusive right

2.5.1. The definition of the exclusive right

- The holder of the Community plant variety right is the only person to make or authorize others to make the following acts:
 - ▶ production or reproduction (multiplication)
 - ▶ conditioning for propagation
 - ▶ offering for sale
 - ▶ selling or other marketing
 - ▶ exporting from the Community
 - ▶ importing to the Community
 - ▶ stocking for the aforementioned purposes

2.5.2. The scope of the exclusive right

2.5.2.1. The protected material

2.5.2.2. The protected varieties

2.5.2.3. The duration of the exclusive right

2.5.2.1. The material protected by the CPVR

- The right relates to:
 - ▶ the “variety constituents” of the protected variety: entire plants or part of plants as far as such parts can produce entire plants
 - ▶ the harvested material (plant or part of plant): only if it has been obtained through the unauthorised use of variety constituents of the protected variety and **unless** the holder has had reasonable opportunity to exercise its right in relation to these variety constituents
 - ▶ If implementing rules provide it: the products obtained directly from the material of the protected variety (jams, flour, fruit cordials...) only if these products were obtained through the unauthorized use of the material of the protected variety and (**unless**) if the holder has had reasonable opportunity to exercise its right in relation to this material

2.5.2.2. The varieties protected by a CPVR

- According to Article 13 of the Regulation, the protection conferred by the Community right covers:
 - ▶ the variety at issue
 - ▶ the varieties that are not sufficiently distinct from the variety at issue
 - ▶ the essentially derived varieties
 - ▶ the varieties whose production requires the repeated used of the protected variety

Essentially derived variety

- A variety is deemed to be essentially derived from another variety, referred to hereinafter as “the initial variety”, when:
 - ▶ it is predominantly derived from the initial variety or from a variety it itself predominantly derived from the initial variety
 - ▶ it is distinct from the initial variety
 - ▶ except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that result from the genotype or the combination of genotypes of the initial variety

2.5.2.3. Duration of the exclusive right

- 25 years as of the grant of the right (Art. 19 Regulation)
- As an exception, 30 years
 - ▶ for “varieties of vine and tree species” (Art. 19 Regulation)
 - ▶ for varieties of potatoes (Regulation (EC) No. 2470/96 of 17 December 1996 extending the duration of the Community plant variety right for potatoes)

2.5.3. The limits of the exclusive right

- Five limitations are laid down to the breeder's rights:
 - 2.5.3.1. The use of the protected variety as source of the initial variety for breeding a new variety (the breeder's privilege)
 - 2.5.3.2. The farm seeds or the farmer's privilege
 - 2.5.3.3. The exhaustion of the holder's rights
 - 2.5.3.4. The acts related to a compulsory exploitation right
 - 2.5.3.5. The acts accomplished for experimental purposes or in private and for non commercial purposes

2.5.3.1. The breeder's privilege

- The privilege
- The status of the new variety
- The limitation to the breeder's privilege

The privilege

- The Community plant variety right does not allow the breeder to prohibit others from accomplishing acts “for breeding, or discovering and developing other varieties” (Art. 15-c Regulation)
- It is the basic principle of the plant variety law; it authorises anyone to use a protected variety as starting material for breeding new varieties
- All the plant genetic resources are of free access and free use to any person which wishes to use them for breeding a new variety
- The aim is to favour and encourage the plant breeding for the benefit of society
- This principle contrasts with patent law

The status of the new variety

- Once a new variety has been bred, its breeder can claim and be granted a full and entire exclusive right (national or Community plant variety right). It can freely use its variety and accomplish all the acts that are subject to the breeder’s monopoly, *i.e.*, propagating, selling...
- Obviously, this breeder’s exclusive right exists only if the new variety satisfies all the requirements of protection and manages to be distinct from the variety used as starting material
- **In the specific case where the new variety is an essentially derived variety, its breeder can be granted a right for it but its exploitation will depend on the authorisation of the holder of the initial variety**

2.5.3.2. Farmer's privilege

- UPOV – an optional exception
- Article 15-2 UPOV Convention 1991:

2) [Optional exception] Notwithstanding [Article 14](#), each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by [Article 14.5\)a\)i](#) or [ii](#).

Article 14 of Regulation No. 2100/94

- For some listed plant species
- Farmers are authorised to use for propagating purposes in the field, on their own holding, the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety
- Free privilege for "small farmers"
- The "other farmers" must pay an equitable remuneration to the breeder, which is sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area

Safeguard of the breeder's interests

- Obligation to pay a remuneration to the breeder
 - ▶ except for small farmers
- The royalty rate is free but must be sensibly lower (50%) than the remuneration requested for the licensed production of propagating material of the same variety in the same area (cf. ECJ, 8/6/2006, Saatgut-Treuhandverwaltung GmbH)
 - ▶ It is determined in an agreement between the breeder and the farmer
 - ▶ The usual royalties serve as guidelines; reference agreements may be published by the UPOV

2.5.3.3. Exhaustion of the holder's rights

- Art. 16 of Regulation No. 2100/94:
- The Community plant variety right **does not extend** to acts concerning any **material** of the protected variety, or of a variety covered by the Community plant variety right, which has been **disposed of** to others **by the holder or with his consent**, in any part of the **Community**, or any material derived from the said material
- Unless such acts:
 - ▶ Involve **further propagation** of the variety in question (except where such propagation was intended when the material was disposed of); **or**
 - ▶ Involve an **export** of variety constituents into a **third country** which does not protect varieties of the plant genus or species to which the variety belongs (except where the exported material is for final consumption purposes)

2.5.3.4. The acts related to a compulsory exploitation right

- Article 17 of the 1991 UPOV Convention permits the grant of compulsory exploitation rights only on grounds of public interest
- Article 15 e) of the Regulation provides that the acts related to a compulsory exploitation right constitute a limitation to the holder's exclusive right
- The Regulation contains four different compulsory exploitation rights

2.5.3.5. Acts done for experimental purposes or done privately and for non-commercial purposes

- Acts done for experimental purposes:
 - ▶ Origin: Art. 15(1)(ii) of the 1991 UPOV Convention
 - ▶ For example, scientific research by university departments but also research undertaken by commercial enterprises, testing varieties under different climatic circumstances or in different types of soil
- Acts done privately and for non-commercial purposes:
 - ▶ Origin: Art. 15(1)(i) of the 1991 UPOV Convention
 - ▶ The production or reproduction of variety constituents or harvested material of the protected variety shall not be an infringing act if it has been done for one's own private garden or glasshouse

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