Community Plant Variety Protection and European Patent Law: the overlaps

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The Community Plant Variety System:
Challenges and Opportunities
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Overview

- Double protection prohibition
- Patentability of plants
- Essentially biological processes: Broccoli & Tomato case
- Products obtained by essentially biological processes: Broccoli II & Tomato II
- Compulsory cross-licensing
- Breeder's exemption

Double protection prohibition

- Article 92 Regulation 2100/94 (Basic Regulation):

  "Any variety which is the subject matter of a Community plant variety right shall not be the subject of [...] any patent for that variety".

- Article 53 (b) European Patent Convention (EPC):

  "European patents shall not be granted in respect of [...] plant [...] varieties or essentially biological processes for the production of plants; this provision shall not apply to microbiological processes or the products thereof".

Non patentable

- Plant varieties *per se*, even as products of microbiological or other technical processes
- Essentially biological processes

Patentable

- Plants
- Microbiological or other technical processes and products thereof except for plant varieties

Definition of plant variety

- Plants ≠ plant varieties
- "Plant variety" is a plant grouping within a single botanical taxon of the lowest known rank, which can be:

➢ Defined by the expression of the characteristics that results 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

(Art. 5(2) BR, Art. 1(vi) UPOV Conv. 1991, Rule 26(4) EPC)

Patentability of plants

- Plants can be patented if the technical feasibility of the invention is not confined to a particular plant variety (art. 4(2) Directive 98/44/EC, Rule 27(b) EPC)
- A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under article 53(b) EPC, even though it may embrace plant varieties (Novartis II, G1/98)
- Inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the EPC (Novartis II, G1/98)

Are hybrids patentable?

- TBA of the EPO: "Hybrid seeds or plants thereof... are not considered as units with regard to their "suitability for being propagated unchanged"... and are therefore not regarded as plant varieties which are excluded from patentability." (case T 788/07)

But

- "Varieties of all botanical genera and species, including, inter alia, *hybrids* between genera or species, may form the object of Community plant variety rights"

  (Art. 5(1) BR)
- In this direction also 1991 UPOV Convention

Essentially biological processes

- T320/87: consider totality of human intervention and its impact on the result achieved → not any kind of human intervention renders a process patentable
- "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) Directive 98/44/EC, Rule 26(5) EPC)
- crossing and selection are not necessarily natural phenomena → not clear definition (G2/07)

Broccoli and Tomato cases (G2/07 and G1/08)

- A classical method for producing plants which contains or consists of sexually crossing the whole genome of plants and of subsequently selecting plants is not patentable

- Adding a technical step merely to enable or assist the performance of the steps of sexually crossing or of selecting does not render such a process patentable

- However, if such a process includes *within* the steps of sexual crossing and selecting an additional technical step which *by itself* introduces or modifies a trait in the genome, the process becomes patentable

Products obtained by essentially biological processes

- No statutory provision regulating this question
- Should the products be patentable since they are not explicitly included in patentability exclusions?
- Should these products be excluded from patentability as a logical consequence of the fact that the process for their production is not patentable?

Tomato II – T 1242/06

- Patentee: no process claims, only product claims (claims directed to tomato fruit)

- Is the product claimed a plant variety?
- Does the exclusion of the process as being essentially biological affect the patentability of the product?

Tomato II – T 1242/06

- TBA: absolute protection conferred by a product claim which encompasses also protection provided by a claim for the process of making the product → product claim protection broader than process claim protection

- In the present case: disregarding 53(b)EPC may result to allowing the broader protection by product claims while the legal framework disallows the narrower protection conferred by claims on essentially biological processes → Risk of circumventing legislator's intention and overcome the process exclusion by presenting product claims

1. Can the exclusion of essentially biological processes for the production of plants have a negative effect on the allowability of a product claim directed to plants or plant material such as fruit?
2. Is a claim directed to plants allowable even if the plants can only be obtained at the filing date through an essentially biological process disclosed in the patent application?
3. Is it of relevance that the protection conferred by the product claim encompasses the production of the plants by an essentially biological process which is excluded from patentability?

Broccoli II – T 83/05

- New requests: process claims deleted, only product-by-process claims submitted for plants and parts of plants obtained through crossing and selection

- New element: disclaimers introduced
  - Doubtful whether European patent law allows such disclaimer/waiver of rights
  - However, this could solve the conflict between plant patentability and exclusion of essentially biological processes

New referral G2/13- Questions

1. Can the exclusion of essentially biological processes for the production of plants have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts?
2. a) Is a product-by-process claim directed to plants allowable even if its process features define an essentially biological process for the production of plants?
2. b) Is a claim directed to plants allowable even if the plants can only be obtained at the filing date through an essentially biological process disclosed in the patent application?

3. Is it of relevance that the protection conferred by the product claim encompasses the production of the plants by an essentially biological process which is excluded from patentability?

4. If a claim directed to plants is not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability, is it possible to waive the protection for such generation by "disclaiming" the excluded process?

Products of essentially biological processes

- The "melon patent" case: Melon plants resistant to a virus produced by the introduction of a gene from another melon plant by way of a conventional breeding method involving the use of a genetic marker ("marker-assisted method")

- EP 1 973 397: Cucurbita plant (zucchini, pumpkins, etc.) comprising a new gene with CMV (cucumber mosaic virus) resistance

- Resolution of the European Parliament on the patenting of essential biological processes (10 May 2012):

➢ Excessively broad patent protection can hamper innovation and be detrimental to breeders

➢ The Parliament called on the EPO to exclude from patenting products derived from all conventional breeding methods (including SMART breeding) and breeding material used for conventional breeding

Compulsory cross-licensing

Article 12(1) Directive 98/44/EC and Article 29(5a) Basic Regulation:

- "Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent."
- Where such licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety

Compulsory cross-licensing

Article 12(2) of Biotechnology Directive and Article 29 (5a) Basic Regulation:

- "Where the holder of a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right."
- "The holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention."

Compulsory cross-licensing

- Provision that is not used in practice

- Conditions for application limit the scope of the provision - The applicant has to demonstrate that:

➢ he has applied unsuccessfully to the holder of the right to obtain a contractual licence, and

➢ the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

Breeder's exemption

- Cornerstone in PVR system:

  Art. 15(c) Basic Regulation & Art. 15 (1) (iii) 1991 UPOV Convention

- The problem of overlaps: risk of unequal situation
  - patentees are entitled to make free use of plant material protected by breeder's rights, to improve that material and to apply for patent protection
  - On the contrary, breeders are not entitled to make free use of such improved plant material as in patent law there is no breeder's exemption but a principle of dependence

Breeder's exemption in patent law as well?

- Several national laws have introduced a "research exemption" covering activities ***on*** the subject matter of the patent for research purposes.
- However, the breeder's exemption goes one step further and allows activities ***with*** the protected subject matter in order to develop a new variety

- Full breeder's exemption?
- Limited version thereof?
- No place at all for breeder's exemption?

Breeder's exemption in patent law as well?

- Art. 27 (c) of the Unified Patent Court Agreement:
- "The rights conferred by a patent shall not extend to [...] the use of biological material for the purpose of breeding, or discovering and developing other plant varieties"

- However, Art. 5(3) of Regulation 1257/2012 stipulates that the exclusive rights and the limitations thereto shall be determined in accordance with the national law applicable, by virtue of Art. 7 of the same Regulation

To be continued…

Thank you for your attention