Netherlands' EU Presidency 2016

Introduction to Patents, Plant Breeders' Rights and the Biotech Directive

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Agenda

I. Coexistence of IP Rights

II. Problems of Demarcation

III. Patent Claims on Native Traits

IV. Scope of Protection

V. Limitations

VI. Conclusions

Coexistence of IP Rights (1)

Plant Breeders' Rights
- **CPVR 2100/94**
- **National PVR**
- **UPOV 1991**

Coexistence of IP Rights (1)

Plant Breeders' Rights
- CPVR 2100/94
- National PVR
- UPOV 1991

Patents
- EPC + Impl. Reg.
- Biotech D 98/44
- National Patents
- UPC + Reg.

Coexistence of IP Rights (2)

- Plant Breeders' Rights or Plant Variety Rights (PVR)

Art 5 II CPVR 2100/94

For the purpose of this Regulation, 'variety' shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, 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.

- **CPVR: Protection for plant varities**

- **No protection for**
  * **Plants of a higher know taxon, e.g. tomato**
  * **DNA or gene sequences, „traits“**
  * **Breeding methods**
  * **Methods of biotechnology**

Coexistence of IP Rights (2)

- **European Patent law:**

Art 3 D 98/44, EPC Impl. Reg., National law

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. 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 4 D 98/44, National law

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.*

2. 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.

Art 4 D 98/44, National law

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*** Germany and the Netherlands go beyond and exclude „essentially biological processes for the production of plants or animals <u>and plants or animals resulting from those processes.“</u>**

Art 53 lit. b) EPC

European patents shall not be granted in respect of:
(a) ...

(b)
plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) ...

Coexistence of IP Rights (2)

- **Protected under European Patent law:**
  * **Biological material including DNA which is isolated from its natural environment or produced by means of a technical process**
  * **„Traits“ of genetically modified plants**
  * **Methods of biotechnology or genetic engineering**

Coexistence of IP Rights (3)

- Prohibition of double proteciton UPOV 1961 + 1978
  * Either patent or PVR
  * Motive for Art 53 lit. b) EPC

- Deletion of prohibition in UPOV 1991
  * Some commentators claimed for deletion of prohibition of double protection in European patent law (Straus 1983 and 1993), but Art 53 lit. b) EPC and Art 4 D 98/44 maintained the principle

- **Questions settled by non-patentability rules:**
  - **No patents on plant varieties → irrespective if resulting from essentially biological breeding or from genetical modification**
  - **No patents on essentially biological processes for the production of plants or animals**

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Problems of Demarcation (1)

- Essentially biological processes for the production of plants or animals – or not?
  * EPO EBOA „Broccoli I“ (2010):
    - SMART breeding
    - Art. 2 II D 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.“
    - EPO: Use of SMART breeding does not change the character of the process as essentially biological
  * But: Genetical modifications, be it characteristic changed or introduced in the plant genome, are not an essentially biological process

Problems of Demarcation (2)

- Product claims on plants, which do not meet the narrow requirements of a variety

  * EPO BOA „Transgenic plant/Novartis II“ (1999): Patent on transgenic plant
  * EPO EBOA „Tomate II“ (2015): Patent on plants resulting from essentially biological process?

Dehydrated Tomatoes

Picture: Wikimedia/Kazvorpal, CC BY-SA 2.0

Enlarged Board of Appeal, 25.3.2015, G2/12 and G 2/13, – Tomatoes II und Broccoli II

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Picture: Wikimedia/Kazvorpal, CC BY-SA 2.0

Enlarged Board of Appeal, 25.3.2015, G2/12 and G 2/13, – Tomatoes II und Broccoli II

EP 1 211 926:
Claims in their last version

1. A tomato fruit of the species Lycopersicon esculentum which is naturally dehydrated, wherein natural dehydration is defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said dehydritation being generally unaccompanied by microbial spoilage.
2. A tomato fruit of the species Lycopersicon esculentum charcaterized by an untreated skin, dehydration of the fruit and wrinkling of the skin, said dehydritation being generally unaccompanied by microbial spoilage.

Flavonol Expressing Tomatoes

Picture: Wikimedia/Fir0002, GFDL 1.2

EP 1 515 600

18.05.2016

Metzger

EP 1 515 600

1. A non-transgenic domesticated L. esculentum plant growing fruits with a content of flavonols in the flesh of the fruit that is greater than 0.5 mg/mg dwt and a content of flavonols in the peel of said fruit of at least 5 mg/mg dwt due to up-regulated flavonol biosynthesis in the fruit flesh of said plant and restored CHI expression in the fruit peel of said plant, wherein said non-transgenic domesticated L. esculentum plant is obtainable by introgressing the CHI gene and the [the] flavonol biosynthesis pathway genes CHS, FSH and FLS of Lycopersicon wild accessions LA1963, LA2884 and LA1926 into a domesticated L. esculentum plant.

EP 1 515 600

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Seedless Pepper

Picture: Syngenta

EP 2 166 833

EP 2 166 833

1. A male sterile hybrid pepper plant, which grows normal-looking edible seedless fruits throughout the whole plant, wherein said seedless fruits are characterized by being at least 95% seedless, wherein the 'seedless' trait is controlled by a genetic determinant and is independent of (...) wherein the said 'seedless' trait is obtainable from a pepper plant selected from the group consisting of Capsicum annuum AR07-F1-56-b; Capsicum annuum AR07-F1-87-b; Capsicum annuum AR07-F1-166-b; Capsicum annuum AR07-F1-171-X; and Capsicum annuum AR07-F1-172-X, grown from seeds deposited with NCIMB, Aberdeen AB21 9YA, Scotland, UK on May 26, 2008 under accession number NCIMB 41558, NCIMB 41559, NCIMB 41560, NCIMB 41561 and NCIMB 41562, respectively.

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Scope of protection

* **Product by process-claims („pbp-claims“)**

  → Claims on native traits after „Tomatoes II“ are drafted as pbp-claims (“obtainable by”), breeding/production with deposited plants

* **Scope of protection of pbp-claims**

  → making, offering, placing on the market of plants or plant parts with the described trait

  → Only products obtained by the same process? Different approaches in Germany, USA, UK

Scope of protection

* **Art 8 Biotech D 98/44**

  - Courts in EU member states will have to apply the standard of Art 8 to patents granted by EPO
  - Does the scope of protection under Art 8 cover biological material comprising the same characteristics but not derived from the plant material of the inventor?
  - Patents in plants use deposits for the description of the invention → basis to narrow down the scope of claims on plant material
  - How to cope with broad, generic claims not described by a deposit?

Art 8 Biotech D 98/44

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention 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.
2. 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.

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Comparison with PVRs

* **Art 13 Reg 2100/94**

2. Without prejudice to the provisions of Articles 15 and 16, the following acts in respect of variety constituents, or harvested material of the protected variety, both referred to hereinafter as 'material', shall require the authorization of the holder:

(a) production or reproduction (multiplication);
(b) conditioning for the purpose of propagation;
(c) offering for sale;

3. The provisions of paragraph 2 shall apply in respect of harvested material only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents.

* Art 5 Reg 2100/94

3. A plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred to hereinafter as 'variety constituents'.

→ *Restricted protection*

- no protection of processes
- no protection of genetic information as such
- protection of plant parts only if capable of producing entire plants
- protection of harvested material only if obtained through unauthorized use
- but: protection covers essentially derived varieties, Art. 13 para 5 Reg 2100/94

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Limitations

* **Limitations of the effects of a patent**

  - **Exhaustion, including biological material obtained from the multiplication of biological material placed on the market by the rightholder (…), Art 6 Reg 1257/2012, Art 10 Biotech D 1998/44**

  - **Experimental use, Art 27 lit b) UPC-Agreement**

  - **Breeder's exemption, Art 27 lit b) UPC-Agreement**

  - **Farmer's privilege, Art 11 para 1 Biotech D 1998/44, Art 27 lit i) UPC-Agreement**

  - **…**

Limitations

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  - **…**

Breeder's exemption

* **Not provided for in the Biotech D 98/44**
  - Some European jurisdictions have implemented limitations for breeders, e.g. Germany, France, Netherlands, but not UK

* **Art 27 lit b) UPC-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."

* **Scope of the exemption**
  - Use of biological material for breeding purposes
  - Use of process claims for breeding purposes?
  - Not making, offering, placing on the markt

→ ***Dependency, but...***

* Compulsory license Art 12 Biotech D 98/44

1. 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 inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. (...)

(...)

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(...)
(b) 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.

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Comparison with PVRs

* **Art 15 Reg 2100/94**

The Community plant variety rights shall not extend to:

(c) acts done for the purpose of breeding, or discovering and developing other varieties;

(d) acts referred to in Article 13 (2) to (4), in respect of such other varieties, except where the provisions of Article 13 (5) apply, or where the other variety or the material of this variety comes under the protection of a property right which does not contain a comparable provision; and

* Art 13 Reg 2100/94

5. The provisions of paragraphs 1 to 4 shall also apply in relation to:

(a) varieties which are essentially derived from the variety in respect of which the Community plant variety right has been granted, where this variety is not itself an essentially derived variety;
(…)

* Scope of the exemption

- **Use of biological material for breeding purposes**
- **Making, offering, placing on the market of new varieties**
- **Not for essentially derived varietes (EDVs)**

→ *No dependency*

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* *Tomatoes II* has opened the door for patent claims on native traits

* Overlaps of patents and PVRs are on the rise

* Policy makers must answer the question if society has an interest in changing the innovation model of the breeding industry and the structure of the European agricultural sector

* But: Patents granted after *Tomatoes II* are narrower in scope

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