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LIFE AT THE INTERSECTION OF PATENT PROTECTION AND PLANTBREEDING

**Forum Conference on
IP Protection for Plant Innovation
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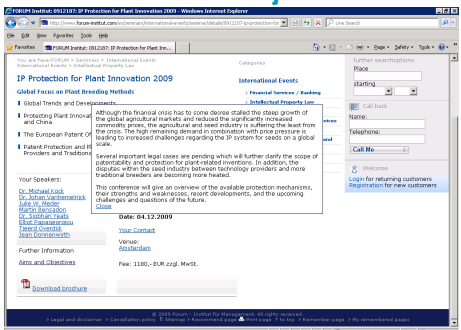
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Outline

- What does the intersection look like?
- Patents;
- Plant Variety Rights;
- Case law;
- Where do patents interfere with plant breeding?

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Conference: Aims and Objectives



The screenshot shows a web browser window with the title 'IP Protection for Plant Innovation 2009'. The page content includes a header with the Vondst logo, a main heading 'IP Protection for Plant Innovation 2009', and several sections: 'Global Forces on Plant Breeding Methods', 'International Events', 'Your Speakers' (listing Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck, Dr. Michael Luck), and 'Further Information' (listing 'Date: 04-12-2009', 'Venue: Amsterdam', 'Fee: 1100,- €/€ incl. lunch').

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Basics of patent system

- Inventions are good and should be promoted;
- Lord Justice Jacob:
“Without a reliable patent monopoly there is simply no incentive to invest.”
- Contract model:
- Invention is awarded with monopoly;
- In return the invention must be published;

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Basics of PVR system

- New varieties of plants and fruits are for the benefit of mankind;
- New variety is awarded with monopoly;
- Publication enables others to determine extent of monopoly;
- Rationale largely same as for patents;
- Longer protection to enable reasonable return on investment.

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Why separate protection systems?

- Rationale for PVRs largely same as for patents;
- Plants are usually a product of nature;
- Difficult to be described in technical terms;
- Mostly incapable of identical reproduction.

Exceptions to patent monopoly:

- Excluded subject matter;
- Research exemption;
- Compulsory licensing;
- No abuse of dominant position;
- Exhaustion principle.

Exceptions to PVR monopoly:

- Non commercial use in private sphere;
- Farm saved seed;
- Scientific research;
- Exhaustion rule: largely similar to rule regarding patents, except:
 - Acts of further reproduction;
 - Export to country without comparable level of protection

Objects of protection of patents/PVRs:

- Products/processes vs. plant varieties;
- For patents many objects are excluded matter; not so for plant varieties;
- The Biotech Directive 98/44 brought important expansion of the realm of patents into the plant related industry;

Case 1: Enza v. Vilmorin: chicory



- Patent EP 771 523 for “A cytoplasmic male sterile vegetable plant cell of the compositae family and also a method for obtaining such plant”;
- Vilmorin sells chicory varieties Goldwin F1 and Crenoline F1.

Case 1: Enza v. Vilmorin


- 1st defence:
- Term “stably expressible cytoplasmic male sterility” requires merely that the genes which are responsible for the CMS property are stably inherited;
- Phenotypical expression not necessary;

Case 1: Enza v. Vilmorin

- 2nd defence:
- Feature “stably expressible cytoplasmic male sterility” is not present;
- Enza claims CMS feature must be there because of presence of Cox II gene from Sunflower;
- Court: unclear which gene is responsible for CMS property. Presence of another gene is insufficient proof that claim is satisfied.

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Case 2: Monsanto v. Cefetra: RR soy meal



- RR-soybean has genes which enable it to make the so-called enzyme CP4-EPSPS, which provides glyphosate tolerance.
- Patent EP 0 546 090 relating to "Glyphosate tolerant 5-enolpyruvyl-shikimate-3 phosphate synthesis";

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Case 2: Monsanto v. Cefetra

- Final amended claims of EP '090 comprise:
 - - one or more **isolated DNA sequences**;
 - - a number of **DNA molecules**;
 - - a **method**, of producing genetically transformed plants which are tolerant towards glyphosate herbicides;
 - - a number of glyphosate tolerant plant **cells** that have certain characteristics;
 - - a number of glyphosate tolerant **plants** that has certain characteristics;

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Case 2: Monsanto v. Cefetra

- Principal defendants: two soy meal trading companies: Cefetra and Alfred C. Toepfer International (ACTI);
- State of Argentina granted leave to join the proceedings as co-defendants;
- Two shipments of soy meal from Argentina seized in 2005 and 2006.

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Case 2: Monsanto v. Cefetra

- Monsanto presented two tests:
 - Test 1: proved the presence of CP4-EPSPS enzyme in the soy meal;
 - Test 2: proved the presence in the soy meal of the DNA sequence which encodes for CP4-EPSPS.

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Case 2: Monsanto v. Cefetra

- Defence 1:
 - The DNA may be present in the soy meal, but not as an isolated substance. Therefore, trading the soy meal cannot constitute a breach of claims 1 through 5.
 - Monsanto argued that DNA sequence has been encoded in the DNA of the soy plant and that the bean meal should be regarded as an isolated DNA sequence, or contains this
 - Court: **no**: isolated DNA as DNA that has been retrieved from the cell (core) of an organism for further treatment as usual in profession.

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Case 2: Monsanto v. Cefetra

- Defence 2:
 - Soy meal cannot be regarded as a product that has been directly obtained by the application of process claims 14, 17 to 19 and 28.
 - Court: **yes**: treatment needed to obtain meal from soy bean has too many steps to assume direct relationship between the method and the soy meal.

Case 2: Monsanto v. Cefetra

- Defence 3:
- Soy meal is dead material, so the DNA present in the soy meal can no longer express its function;
- Biotech Directive preamble paras 23 and 24;
- Explanatory letter from E.U. Commission;
- Explanatory notes Dutch implementing bill;
- Parallel decision by Spanish Court.

Case 2: Monsanto v. Cefetra

- Counter-arguments Monsanto:
- First: soy meal is no biological material. Therefore, the Biotech Directive would not apply and the infringement must be determined on the basis of the basic provisions relating to the scope of protection, which provide full protection to the product, the patented DNA sequence;
- Alternatively: Expressing function: has occurred in the past or may occur in the future.

Case 2: Monsanto v. Cefetra

- Court regarding defence 3, alternative issue:
- Look at patent and not at infringing material;
- Patent has been granted for biological material, so articles 8 and 9 Biotech Dir. apply;
- Court is in limbo as to meaning of exercising its function and seeks guidance from ECJ;

Case 2: Monsanto v. Cefetra

- Court regarding defence 3, first issue:
- In view of various reasons Court is inclined to accept Monsanto's arguments.
- However, the court finds the indications for this interpretation not sufficiently clear and wishes to receive guidance also on this issue.

Case 2: Monsanto v. Cefetra 2 principal questions to ECJ:

- Is element "and performs its function" also covered when the product (the DNA sequence) does not perform its function at time of infringement, but has done so in the past or would be able to do this again?
- Is protection under art. 9 Biotech Dir. not exhaustive and is it possible that national patent laws offer an additional protection to the product as such (such as isolated DNA), regardless of requirements under Article 9 of the Directive (in the situation in which the product consists of genetic information or contains such information and the product is incorporated in material which contains the genetic information?)
-

Case 2: Monsanto v. Cefetra: Commentators:

- Sven Bostyn (October 2008):
 - This is direct and straightforward infringement of product claim under regular rules concerning scope of protection;
 - No need to ask questions to ECJ;
- Erik de Vos (September 2009):
 - Article 9 sets limitation to regular scope of protection;
 - No protection in case the DNA does not perform its function in the product;
 - No room for application of regular infringement test.

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Collision issues:



- Extended possibilities for protecting biotech inventions lead to substantial increase of material overlap of patent rights and the world of plant breeding.

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Why do collision issues arise?

- Biotech Dir. provides for compulsory cross licensing;
- Biotech Dir. provides for farmer's privilege;
- However, Biotech Dir. lacks Breeders' Exemption;
- 'Breeder's world' sees Breeders' Exemption as perfect balance of interests;
- Breeders' Exemption is form of open innovation and serves best the general interest of continuous improvement of plant varieties which are **immediately available** for further improvements by other breeders.
- In case of patent breeders have to wait **20 years!**

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Patents do increasingly form an obstacle to plant breeding.

- Is it a problem?
- If it is a problem, is it a serious problem?
- Does it require a structural solution?
- There are hardly any disputes that go to court!
- Should number of known legal disputes be considered decisive?


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There may be a lot more confrontations that we do not know about!



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The result may typically be like this (where you may guess who runs the AmTrack)



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Patents as obstacles to plant breeding sees increased attention:

- Questions in Dutch Parliament;
- Limited exemptions in Germany and France are seen as virtually useless;
- Rules regarding compulsory licences too strict: practical application seems zero;
- Biotech companies strive to abolish even the limited exemptions;
- Convergence of biotech companies and traditional breeding companies;

Plantum NL Position on patents and PVRs

- 1. Biological material protected by patent rights should be freely available for the development of new varieties.
- 2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.
- 3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.

Conclusions:

- Patents do increasingly form an obstacle to plant breeding, which was to be expected;
- Interested circles see it as a problem;
- Unclear whether it is a serious problem;
- Not many disputes reach the courts;
- There is little information on other types of battles. Transparency is needed;
- Amendment of Directive is difficult;
- We need other creative solutions before problems get out of hand.

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