Research exemption in patent law versus breeder's exemption in plant variety protection law

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Outline

- Back in time
- Research exemption in patent law
- Breeder's exemption in plant variety protection law
- Era of biotechnology/Biotech Directive
- The interface problem
- Some legislative solutions
- Stakeholder's initiatives

Back in time

- First patent laws: non-living matter

- Early possibilities to protect plants through patents:
  - Plant Patent Act (USA, 1930)
  - Patentgesetz (Germany, as from 1930)
  - Loi du 5 juillet 1844 (France, as from 1949)

- Early plant variety protection laws:
  - Kwekersbesluit (Breeders' decree) (Netherlands, 1941)
  - Sortenschutzgesetz (Germany, 1968)
  - Plant Varieties and Seeds Act (Great Britain, 1964)

Back in time (2)

- Reasons for *sui generis* protection of plant varieties

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

  ‘ European patents shall not be granted in respect of:
  (...)
  (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.’

  (cf. Article 2(b) of the Strasbourg Convention)

Research exemption in patent law

- Provision laid down in many national patent laws and in Article 27(b) UPC Agreement:

'The rights conferred by a patent shall not extend to any of the following:
(...)
(b) acts done for experimental purposes relating to the subject-matter of the patented invention'

Research exemption in patent law (2)

- *Perhaps* the following trials may be regarded as '*experimental use*': trials carried out

a. in order to discover something unknown; ***or***

b. to test a hypothesis; ***or***

c. to find out whether something which is known to work in specific conditions will work in different conditions; ***or***

d. to find out whether the experimenter could manufacture commercially in accordance with the patent (examples taken from a UK court case)

Breeder's exemption

- Principle:

  - A breeder is completely free to use plant material of protected varieties for the purpose of creating other varieties

  - *and* for the subsequent marketing of such new varieties.

  - He for his part is not entitled to oppose the use of plant material of his own protected variety by other breeders for the same purposes.

  - This rule is also known as the *principle of independence*: the plant breeder's rights granted in respect of these varieties are totally independent from one another.

Breeder's exemption (2)

- Reasons:

  - free access to protected varieties stimulates plant breeding

  - for the development of new plant varieties already existing plant material (protected or not, wild or cultivated) must be available for a breeder, because otherwise he will not be able to create better varieties.

Breeder's exemption (3)

- Legal provisions:

- Article 15(1)(iii) UPOV 1991:

'[Compulsory exceptions] The breeder's right shall not extend to (...) (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to Article 14(4) in respect of such other varieties.'

Breeder's exemption (4)

- Legal provisions (cont.):

- Article 15(c) and (d) Regulation (EC) No. 2100/94:

  'Limitation of the effects of Community plant variety rights

  The Community plant variety right 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 (...)'

Era of biotechnology/Biotech Directive

- Background:

  - Differences between the patent systems of the EU Member States
  - Already many biotech patents in the U.S.A. and Japan

- Very controversial subject matter, as far as the patenting of (parts of) humans and animals is concerned

- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 (Biotech Directive)

Era of biotechnology/Biotech Directive (2)

- Transgenic plant/Novartis II (Enlarged BoA EPO, 20 December 1999, Case G 1/98):

  '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.'

The interface problem

- What *is* the interface problem?

  - Among other things, just for today's presentation: plant variety protection law contains a breeder's exemption, but patent law doesn't.

  - In other words: for a patent holder plant material protected by PBR is freely available for the purpose of improving it, whereas the holder of a PBR cannot make use of patented plant material for breeding purposes, unless paying a licence fee

Some legislative solutions

- a. Broad interpretation of the research exemption in patent law?

- Many differences between member states

E.g., sometimes it is argued:

a. that the privilege only covers scientific research about the invention, i.e. to check whether or not the invention works; ***or***

b. that research for commercial purposes but not for testing the economic value of an invention is also allowed; ***or***

c. that research to enable a quick use of the invention after the expiry of the patent, i.e. clinical research for pharmaceuticals to get data for the admission after the expiry of the patent is also allowed.

Some legislative solutions (2)

- b. Overlap between research exemption and breeder's exemption?

- ***No*** : e.g. in France and the Netherlands: the common understanding in those countries is that the research exemption applies only to experiments '*on*' the patented subject-matter but not '*with*' that subject-matter.
- ***Yes*** : e.g. in Belgium where the provision reads: 'The rights conferred by a patent do not extend to acts that are committed *on and/or with* the subject matter of the patented invention for scientific purposes.'

Some legislative solutions (3)

- c. Amending national patent laws?

Introduction of only the first part of the breeder's exemption in patent law:

'The rights conferred by a patent shall not extend to any of the following:
(...)
(c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties' (Article 27(c) UPC Agreement)

Similar provisions in Swiss, German, French and Dutch law

Some legislative solutions (4)

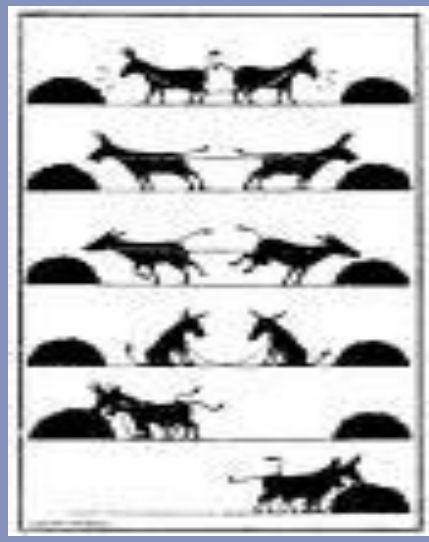
- Introduction of only the first part of the breeder's exemption in patent law can be:

- disadvantageous to *breeders*: the exception does not extend to the subsequent commercialization of the new variety.

- disadvantageous to *patent holders*: they receive payment only when the results of the breeding programme are exploited; that might be near the end of the period of protection.

- Recent initiatives undertaken by the Dutch government

Stakeholder's initiatives



- Contractual licences?

- Can be disadvantageous to breeders:

  - obligation to pay royalty percentages
  - royalty percentages may be rather high
  - no guarantee that a licence will be granted
  - possibility of multiple patent holders
  - interpretation of patents

Stakeholder's initiatives (2)

- International Licensing Platform: to be discussed in one of the next presentations!

Thank you for your attention!

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