

Plant breeding and Intellectual Property Rights – a brief introduction

Plant Breeders' rights and patents

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IPR in plant breeding

- Two independent systems of IP protection:
 - Plant breeders' rights (only for plant and mushroom varieties)
 - Patents (for all inventions with practical use)
- Various other regulations may affect trade (independent of whether or not the variety or material has IP protection)
 - VCU (value for cultivation and use)
 - Seeds and propagules (certification: purity, absence of diseases, etc.)
 - Trademarks ®, 'club varieties', contract production, etc.

VCU assessment is obligatory for obtaining an enlistment on the European Varieties List for arable crops (e.g. wheat, sugar beet, potato); only those varieties can be cultivated in the EU. New additions should be an improvement compared to the varieties on the list.

IPR in plant breeding – two systems

- Plant Breeders Rights (PBR, UPOV convention 1961,..., 1991)
 - Protection of varieties conforming to DUS
 - Distinctness, Uniformity, Stability
 - What is protected is fixed (commercial use of the variety, e.g. seed multiplication)
 - Protection max. 25 years or 30 years
 - Farmers' privilege
 - 'Breeders' exemption': one can freely cross with these varieties, select a new combination, and apply for breeders' rights yourself

DUS: for being recognized as a new variety, it needs to be Distinguishable from all other known varieties based on a set of mainly morphological characters, the plants need to be Uniform for these characters according to demands set by the reproductive system of the crop (e.g. selfing, outcrossing, clonal) and the Variety needs to be Stable for these characters, i.e. after multiplication and when cultivated in two years. Farmers' privilege is the right to multiply seeds for own use. Rules vary per country, as is the extent to which there is a practice of farm-saved seeds. This is an important aspect in discussions around farmers autonomy, particularly for smallholders in developing countries. There are special arrangements for varieties that differ in one trait from existing varieties, e.g. colour mutants in apples and ornamentals, so-called "essentially derived varieties" to protect the interests of holders of the original varieties.

IPR in plant breeding – two systems

▪ Patent law

- Protection of technical inventions
 - Novel, Inventive, Useful
- Prohibits commercial use by others of methods and/or material made with the invention according to claims formulated by applicant
- Claims are evaluated by a patent officer and can be challenged by others
- No farmers' privilege, no breeders' exemption
- Cannot protect varieties, breeding methods that are 'essentially biological' (crossing and selection) in EU



In some jurisdictions, e.g. NL, DE, FR, recently, a limited breeders' exemption was enacted, i.e. one may cross with proprietary plant material but for commercialization of resulting products containing the claimed invention, one needs a license from the patent holder.

IPR in plant breeding

■ Societal debate

- Intellectual Property Rights (with patents) may hinder availability of genetic resources,
 - thus hampering progress in breeding
 - potentially narrowing down crop genetic diversity
- On the other hand, protection important to ensure return on investment,
 - thus sustaining continuing innovation



Two types of ethics may be involved, which is similar to the GM debate. Ethics of principles can view a plant as a living organisms capable of spontaneous reproduction in which only minor adaptations are made by the breeder, which can be summarized in the adage “Kein Patent auf Leben” (“no patent on life”). Consequentialism (pragmatic ethics) often concerns the results of IP: Power relations, e.g. large vs. small companies: patent licensing involves complex negotiations, patents add a need for costly scrutiny of any new germplasm introduced into a company; increased need for record keeping on germplasm used; on the other hand, small start-ups dependent on a strong IPR position (relatively rare in plant breeding).

Gene banks value the free use of their germplasm collections. Thus, the Netherlands gene bank CGN uses an MTA that aims to prohibit patenting if it affects the free use of their material: Article “6.2 The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System”

Patents in plant breeding - issues

- In recent years, it has become more common to patent outcomes of conventional breeding, so-called "native traits", traits already present in the germplasm naturally or producible by recombination
 - Incentives may come from costly new technology used (e.g. MAB: DNA marker-assisted breeding)

Patents involving transgenic plants were already common (see GM debate ppt). In Europe, patenting plants' native traits were subject of debates. Among companies, there was disagreement about the desirability of patents involving native traits. On the one hand, e.g. introducing valuable traits from wild species is challenging whereas once present in commercial material such traits can be relatively easily crossed into the competitor's plant material, so PBR would not suffice to assure sufficient revenues; on the other hand, the open innovation of PBR would serve efficient innovation most optimally. Partial solutions were sought in more transparency about patents and licensing (e.g. ESA's PINTO database of plant patents, e-licensing at the company's website, the International Licensing Platform (ILP) Vegetable negotiated by a number of vegetable breeding companies).

Patents in plant breeding – native traits

- In European patent law, there is an exemption for breeding relating to native traits: so-called “essentially biological processes” are not eligible for patenting
 - “A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection”.
 - The interpretation of this exemption has been the focal point for coming to a solution in the native traits issue.

Patents in plant breeding – native traits

- In recent years, stepwise, the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) came to the interpretation
 - Crossing & selection methods are exempted
 - **However**, the plants themselves are eligible for patenting

- In 2016, the European Commission came to the interpretation that plants from “essentially biological processes” are not eligible for patenting
 - In 2017, EPO decided to follow this interpretation of EC

Reasons for plants deemed being patentable by the lawyers at the EPO after all: the exemption applies to “processes”, and only explicitly exempts plant & animal varieties, not plants in general, plants could be inventive by themselves for patentability (product or so-called “product-by-process”). Technical steps (e.g. use of DNA markers) in the selection process were deemed irrelevant for the exemption, though patentable by themselves. The EC’s line of reasoning was based in history of the development of the exemption: when drawing up the Biotechnology Directive of 1998, it has never been the intention to allow patenting of plants produced by “essentially biological processes” of crossing and selection.

Most likely, directed genomic changes still count as patentable, even though novel techniques of genome editing: e.g. CRISPR-Cas etc., produce genome-edited products that are basically indistinguishable from natural mutants or from products of classical mutagenesis (which are also patentable as “directed” genome change).

IPR in plant breeding – recapitulation

- Two systems of IP protection:
 - Plant breeders' rights (only plant and mushroom varieties):
 - Commercial use of varieties is protected but further breeding is basically free
 - Patents
 - License needed for further breeding
 - Plants with native traits presently not eligible for patenting in Europe
 - GM plants still eligible for patenting

Outside Europe, plants with native traits may still be patentable, e.g. in the US. Patentability of GM plants in Europe will be possible in the widest sense, so for instance including mutagenesis and cell fusion.