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Plant breeding and Intellectual Property Rights – a brief introduction

Plant Breeders' rights and patents

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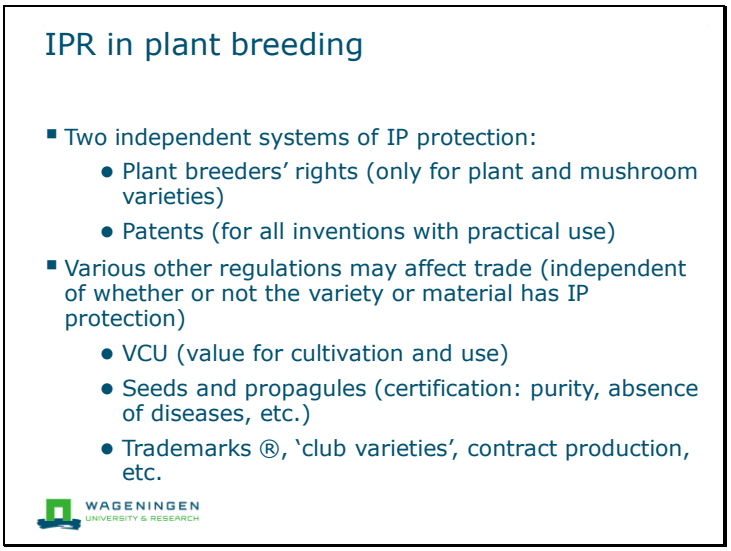

VCU assessment is obligatory for obtaining an enlistment on the European Varieties List for arable crops (e.g. wheat, sugar beet, potato); only those varieties can be cultivated in the EU. New additions should be an improvement compared to the varieties on the list.

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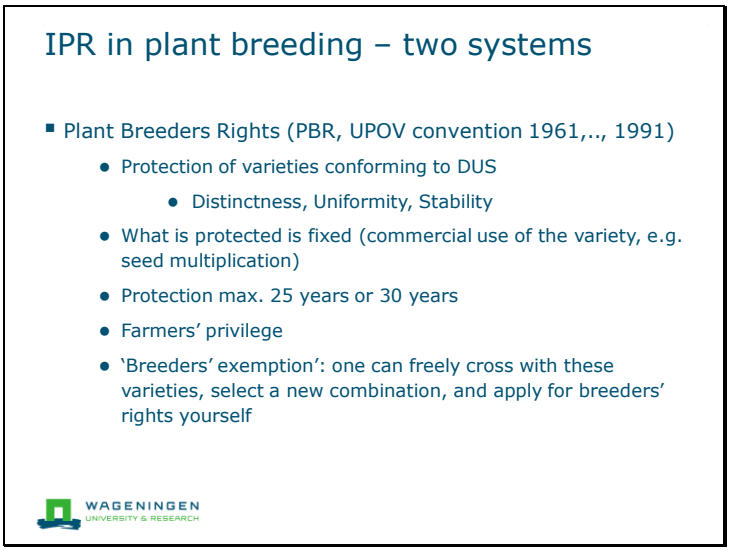

DUS: for being recognized as a new variety, it needs to be Distinguishable from all other known varieties based on a set of mainly morphological characters, the plants need to be Uniform for these characters according to demands set by the reproductive system of the crop (e.g. selfing, outcrossing, clonal) 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.

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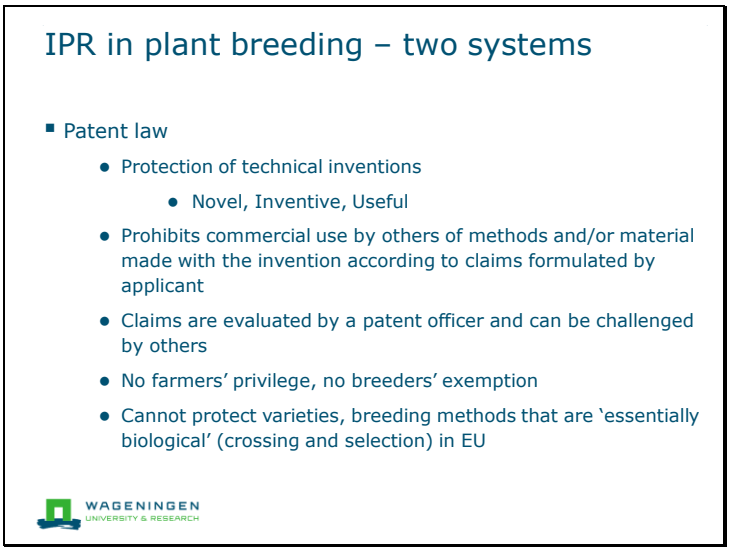

In some jurisdictions, e.g. NL, DE, FR, recently, a limited breeders' exemption was enacted, i.e. one may cross with proprietary plant material but for commercialization of resulting products containing the claimed invention, one needs a license from the patent holder.

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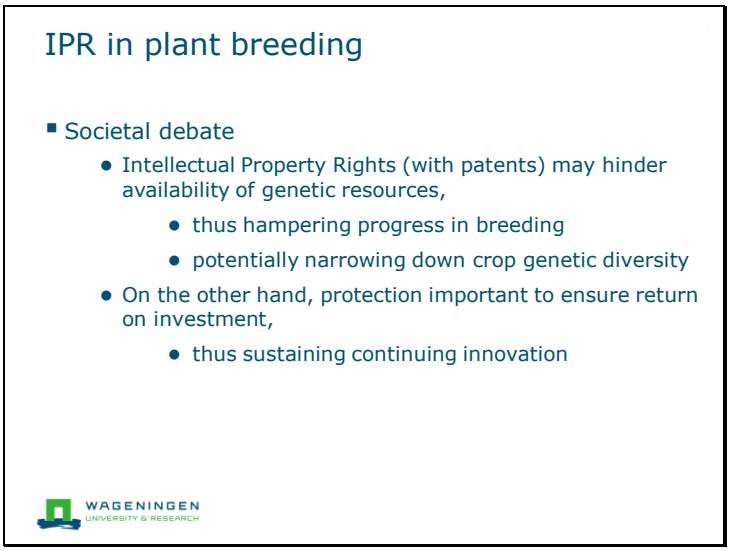

Two types of ethics may be involved, which is similar to the GM debate. Ethics of principles can view a plant as a living organisms capable of spontaneous reproduction in which only minor adaptations are made by the breeder, which can be summarized in the adage “Kein Patent auf Leben” (“no patent on 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”

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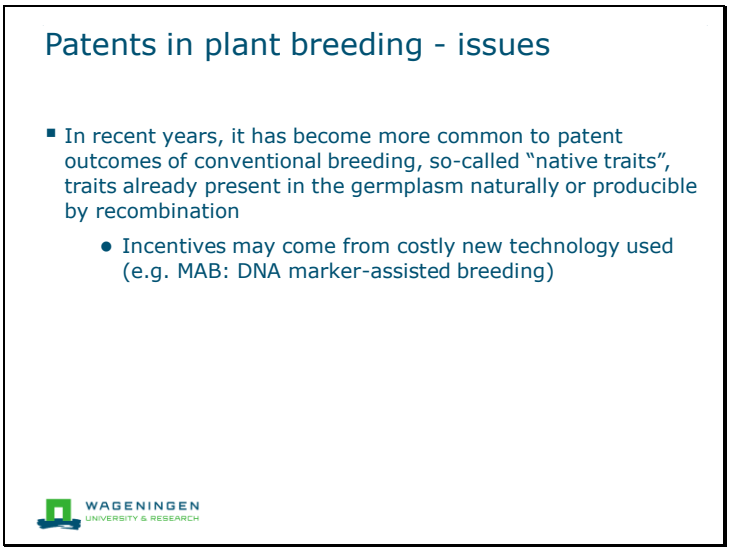

Patents involving transgenic plants were already common (see GM debate ppt). In Europe, patenting plants' native traits were subject of debates. Among companies, there was disagreement about the desirability of patents involving native traits. On the one hand, e.g. introducing valuable traits from wild species is challenging whereas once present in 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).

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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.

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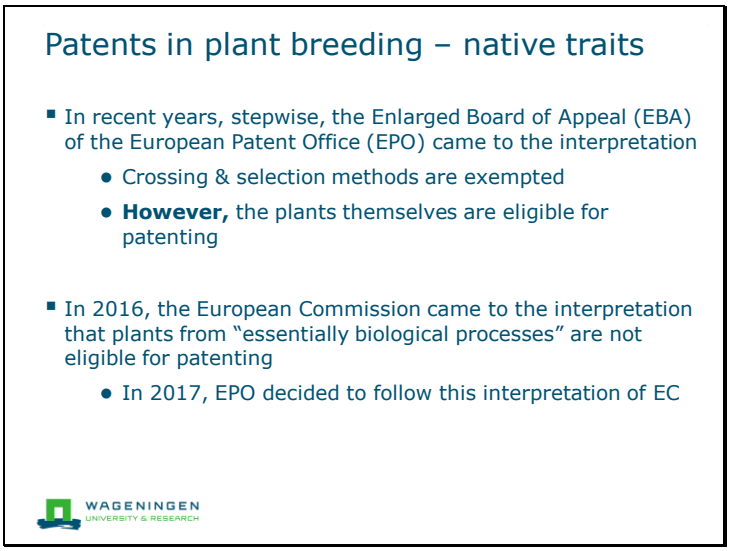

Reasons for plants deemed being patentable by the lawyers at the EPO after all: the exemption applies to "processes", and only explicitly exempts plant & animal varieties, not plants in general, plants could be inventive by themselves for patentability (product or so-called "product-by-process"). Technical 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 of from products of classical mutagenesis (which are also patentable as "directed" genome change).

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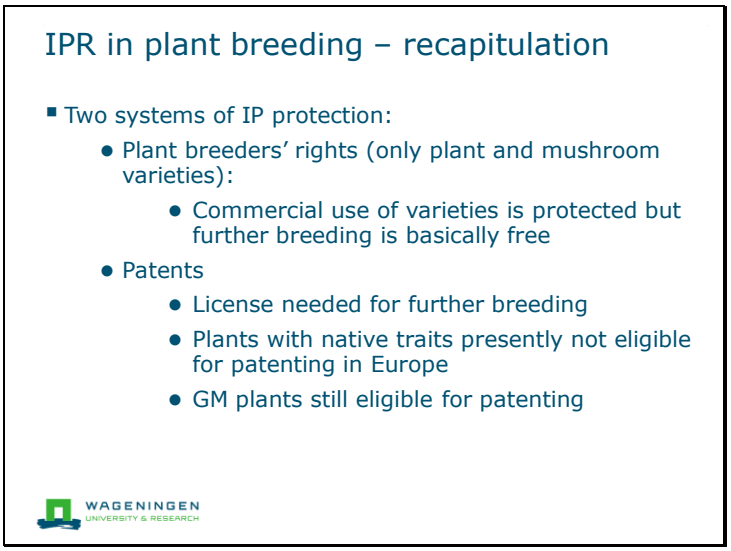

Outside Europe, plants with native traits may still be patentable, e.g. in the US. Patentability of GM plants in Europe will be possible in the widest sense, so for instance including mutagenesis and cell fusion.