GMO’s Patentability in USA

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• GMOs
• US patent system: focusing on agricultural biotechnologies
• From *product-of-nature doctrine* to patentability of living matters
• Patent misuse doctrine for protecting farmers
• Open source system for agricultural biotechnologies
What is a Genetically Modified (GM) Food?

- Foods that contain an added gene sequence
- Foods that have a deleted gene sequence
- Animal products from animals fed GM feed
  - Products produced by GM organisms
GMO: Why are they made?

**Improved crop quality**
- Development of frost resistant crops
- Development of disease resistant crops
- Development of flood resistant crops

**Improved nutritional quality**
- Development of foods designed to meet specific nutritional goals

“Golden Rice” (2000-2008)

beta-carotene, a precursor of vitamin A, in the edible parts of rice.

consumed in areas with a shortage of dietary vitamin A, a deficiency which is estimated to kill 670,000 children under the age of 5 each year.
GMO: Why are they made?

Easing of world hunger
• Development of crops that can be grown in marginal soil

Reduced strain on nonrenewable resources
• Development of drought resistant crops
• Development of salt-tolerant crops

Reduced use of pesticides and herbicides
• Development of pest resistant crops
  (Ex. BT Corn or BT Soy)
Development of weed resistant crops
  (Ex. Round-up Ready)
GMO: Do they affect the environment?

- Certain gene products may be allergens, thus causing harm to human health
- Introduction of toxins
- Alteration in nutrition profile of the food
- There may be unintended harm to wildlife and beneficial insects
- Insects might develop resistance to pesticide-producing GM crops
- Herbicide-tolerant crops may cross-pollinate weeds, resulting in "superweeds"
- Contaminates organic crops
- Creates nutrient-deficient soil
GMO: Where are they grown?

The World's Biggest GMO Lovers
Top GMO crop growing countries, in million hectares (2012)

Source: ISAAA
Which foods contain GM product?

U.S. crops genetically modified according to the USDA in 2011:

- 94% soy
- 88% corn
- 90% cotton

From the U.S. product-of-nature doctrine to the patentability of living organisms.
Title 35, USC § 101:

‘Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title’.
Chakrabarty’s case

• Ananda Chakrabarty, a microbiologist at General Electric Company filed a patent application relating to microorganism having multiple compatible degradative energy-generating plasmids and preparation thereof.’

• Applying the product-of-nature doctrine, the PTO rejected the patent application, claiming that the microorganisms in question were a product of nature, belong to the category of the living organisms. Living organisms were not patentable subject matter under Section 101 of Title 35 U.S.C.
• After his appeal, The Supreme Court of United States held that microorganisms belong to the category of 'manufacture or composition of matter within the meaning of 101'. The Court ruled that Congress, in choosing terms as manufacture or composition of matter, chose the 'expansive terms, which can encompass between statutory subject matters 'anything under the sun made that is by man'.

• The Supreme Court case was argued on March 17, 1980 and decided on June 16, 1980. The patent was granted by the USPTO on Mar 31, 1981.
• After Chakrabarty’s case living invention can obtain patent, but there were some problems about the patentable of vegetable inventions, because there were other specific acts for vegetables.

• We have to mention the Hibberd case. It was a first situation after Chakrabarty’s case, when somebody filed a patent application concerning a GM corn, and granted a patent. The PTO didn't granted the patent at first, because the will of the Congress was to protect this inventions with PPA or PVPA. Finally, The Board of Patent Appeals overturned the decision of the PTO, allowing the utility patent to Hibberd. It was administrative decision.

Utility patents on vegetables
• Pioneer: producer of seeds for agriculture, held seventeen utility patents on seeds of maize hybrids

• J.E.M: bought patented seeds from the Pioneer and resold them. After this was sued for breach of the Utility Patent. The arguments of J.E.M. focuses on the PVPA, arguing that the history of this confirms that the plants reproduce sexually, just as those patented by Pioneer, would be protected only with the certificate issued by the Department of Agriculture.
Judge’s statement:

The system of protection of biotechnological inventions plant becomes full: the PPA was gradually joined by the Trade Secret, the PVPA and ultimately the utility patent, recognizing inventors of a genetically modified plants absolute protection for their inventions.
GMOs and Farmers’ Protection

- Farmer’s privilege absence
  - no right to save 2nd generation seeds

- Patent exhaust doctrine (*Univis* case, 1942)
  - authorized sale
  - unconditional sale
How to avoid patent exhaustion in self-reproducing inventions

- **Single-use restrictions for GMOs seeds**
  - based on the *Mallinckrodt* doctrine

- **Court of Appeal for the Federal Circuit**

- **Supreme Court of the United States**
  - Bowman v. Monsanto (2013)

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Inexhaustible right to exclude reproduction doctrine
Patent misuse doctrine

• Equity

• Avoid the extension of monopoly behind the scope of patent law

• Contrast antitrust practice, but not only
  • e.g. price fixing, tying, post expiration royalties
Patent misuse doctrine and GMOs

- Difficult application for *single-use restrictions*
  - Inexhaustible right to exclude reproduction doctrine extends, automatically, patent to 2nd generation of seeds

- Tying practices relating to seed
  - Are different products tied?
  - Is there power market in the principle product market?
  - What are the effects in the tied product market?
Open source system for biotechnologies:

- turns the idea of the patent monopoly,
- is available for free,
- arises from IT,
- promotes "technological evolution",
- can help to avoid the risk of dependence on agriculture seed industry.

For farmers Open source system does not exist yet, for now it is an idea.
Challenges:

• to obtain an access to intellectual property rights for farmers, which usually do not have this opportunity,

• to create an efficient system of open source licenses and to ensure access to this system for so many farmers and researchers as possible.
Thank you.