

# Life patents and biotechnology- EU and US

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# Biotechnology

- Biotechnology = *“the use of living organisms, (eg bacteria), or the enzymes produced by them, in the industrial manufacture of useful products, or the development of useful processes, eg in energy production, processing of waste, manufacture of drugs and hormones*

# biotechnology

- The production of useful products from living micro-organisms and cell cultures
- Connected to work involving changes to the genetic make up of an organism-genetic engineering
- So we have: new drugs (human insulin, interferons, vaccines, treatments for many diseases)
- Also: controversy

# ..related to DNA

- deoxyribonucleic acid (DNA)
- isolation in 1869 by Friedrich Miescher,
- discovery of its structure and function-1953 by J. Watson and F. Crick
- Biotechnology =a 'road' for innovation
- But also, a reason for many concerns...

# Kinds?

- biotechnology - pharmaceuticals, where micro-organisms are used to produce medicine
- production of insulin, using human cells, instead of cells of pigs
- more than half of the new medicines are related to biotechnologies
- cloning, diagnostics and testing of some genetic diseases such as breast cancer, gene therapy, xenotransplantation, genetically modified seeds and foods
- some new environmental techniques-the creation of micro-organisms which can degrade hydrocarbons.

# Biotechnology and patents

- Subject matter:
- Biomatter – includes products of biotechnology
- Methods/processes to make the matter and products
- Uses of the matter and the products of biotechnology

# Patents?

- A trade-off:
- The State offers an exclusive right to the patent
- In return, the inventor discloses the details of the patent to the public at large, so that progress is allowed
- 20 years---patent system in most countries--  
more sophisticated in some

# Biotechnology patents

- Subject matter (to patent)
- DNA sequences?
- Microorganisms?
- Genetically modified organisms?
- Plant varieties?
- Animal varieties?
- If they are produced via biotechnology

# US system

- Patentable subject matter=inventions related to any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof
- Diamond v Chakrabarty=anything under the sun that is made by man is patentable
- A US Supreme court 5-4 decision...
- Certain: a patent may be granted to living matter IF it is a product of human inventive interference

# Life patents in the US

- Virus
- A single cell
- A multi-cellular organism
- A plant
- An animal
- Novelty?
- Discovery----invention

# EU and patent regulation

- European Patent Convention
- Directive for biotechnology patents 99/44/EC
- National statutes of the member states
- TRIPS

# Life patents in the EU

- European Patent Convention-art 52 (1)
- European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step

# Art 52(2)

- Discoveries cant be patented
- Pure products of nature are not patentable
- A technical aspect of the invention is necessary=if it exists, then we can have an invention
- Discoveries=enhance knowledge
- Inventions=increase the technical skill

# Art 53(a)

- Inventions contrary to public order (ordre publique) or morality
- Cannot be patented
- (b) excludes plants-animals from patenting
- European Biotechnology Directive=also has exceptions for inventions contrary to the public order or morality

# Directive-ordre publique and morality

- Cloning of human beings=no patent
- Modification of the human germ line=no patent
- Using human embryos for industrial or commercial purposes=no patenting
- Genetic modification of animals that causes them suffering without substantial medical benefit=no patenting
- Human body/parts/gene sequences-no patent

# cases

- Diamond v Chakrabarty-5-4-bacteria 'eating' crude oil
- A microorganism is a composition of matter or manufacture even if it is alive.
- A composition of matter is all compositions of two or more substances-all composite articles
- An expansive construction of the patent statute
- On plants, previous statutes: 1930 Plant patent act, only for asexually reproduced plants
- 1970 plant variety protection act-patents for sexually reproduced plants but NOT bacteria

# Hard dissent of 4

- The nation dislikes monopolies but does want to encourage progress
- We need a narrow construction of the statute
- The courts should leave this to the Congress
- Newly developed organisms do not occur naturally but if they could have been patented, there would be no need for the special patent statutes of plants
- Plants are like these bacteria here-not naturally occurring

# Ex parte Allen 1987

- Polyploid oysters with three sets of chromosomes instead of two
- Are patentable subject matter
- Board of Patent Appeals and Interferences
- The UPSTO announces it will consider applications for non naturally occurring non human multi-cellular living organisms, including animals, to be patentable subject matter

# Harvard onco-mouse 1988

- Patent to a mouse—a transgenic non human mammal whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal
- The patent claim excluded humans---for moral reasons and legal ones---
- The US Patent Office granted the patent

# Europe

- European patent convention=no specific rule on living matter and patents
- Clear: the discovery of a substance which exists in nature is this: a simple discovery-no patent
- If one separates the substance of its environment and develops a method-yes
- (directive art 3 par 2)

# Greenpeace v. Brustle

- Brustle had a patent since 1997 on isolated neural cells produced from human fetal stem cells, used to cure neurological damage
- Research on Parkinson's disease
- Greenpeace sues against this patent-ECJ:
- There can be no patent in the cases where the application of the invention has as a consequence the destruction of human embryos
- This is the case if these stem cells here-if you take these stem cells, you need to destroy the embryo...
- The same: you can't use embryos for an invention.
- Kant-don't use people as means-but as ends

# Myriad Genetics case

- Patenting the human genome?
- Genes BRCA1 and BRCA 1
- Myriad has patent rights to the test
- High cost of this test (patent)
- ACLU files against the patent
- Wins-loses-wins in Supreme Court in 2013
- Voided the patents—did allow patents on cDNA (synthetic DNA)

# Against life patents

- Against patents in general: many initiatives
- (open software etc)
- No Patents on Life initiative (council for responsible genetics)
- Greenpeace very active-ACLU also

# Biopiracy?

- opposition to the granting of patents on biological materials such as genes, plants, animals and humans
- Farmers and indigenous peoples are outraged that plants that they developed are being 'hijacked' by companies
- Groups - religious leaders, parliamentarians and environment NGOs are intensifying their campaign against corporate patenting of living things
- A South-North opposition/and a west-east one

# The neem tree

- In Washington in September 1995
- more than 200 organizations from 35 countries filed a petition at the US Patent and Trademark Office
- pesticide extract from the neem tree-patent-application to annul
- They argue that the company has wrongfully usurped an age-old biological process used by millions of farmers in India and other countries for generations.
- The legal challenge is led by the US group Foundation on Economic Trends led by Jeremy Rifkin
- Also: the Research Foundation for Science, Technology and Natural Resources Policy (RFSTNRP) --- Karnataka Farmers' Union (both from India),----the International Federation of Organic Agriculture Movements (IFOAM)----- Third World Network.

# A Swiss case

- Swiss Supreme Court
- The manzana variety of the camomile plant may not be patented.
- Revoked the patent that the Swiss patent office had granted in 1988 to the German pharmaceutical company Degussa/Asta Medica on its manzana variety.
- The case had been brought to court by a Swiss farmer Peter Lendi, president of the Bio-Herb Growers' Association

# And TRIPs?

- The WTO's trade-related intellectual property rights (TRIPs) agreement
- TRIPs has ambiguous language in its clause on living organisms
- patenting of microorganisms is compulsory
- plants and animals can be excluded by the member state patent statute
- but protection of one kind or another is required for plant varieties

# Ethics?

- The patenting of genes is a controversial issue in terms of bioethics
- There are three main concerns voiced about genetic patenting.
- some believe it is unethical to patent genetic material because it treats life as a commodity.
- some say that living materials occur naturally, and therefore cannot be patented.
- fear that allowing patents on genetic material will undermine the dignity of people and other animals by subjecting their genes to ownership by other people.

# But...

- not allowing patents on biotechnological inventions could also be unethical
- patents allow the public, as well as policy makers, to hold the owner of the patent(s) accountable.
- biological patents require disclosure of information to the public
- Balance?

# US –a change?

- SC/NY State Court: ‘isolated DNA of genes is not different from DNA that exists in nature’
- Only the technique of isolating a gene sequence is not enough to differentiate the isolated DNA from DNA in nature
- Information on the natural sequence and in the sequence which is isolated is the same
- CA: the technique of isolating a sequence is a a fortiori case to grant a patent because after isolation, the gene sequence is a separate product, clear from natural elements, and it has a different name/use/utility.