

■ USPTO/UPOV TRAIN THE TRAINER COURSE

The use of plant variety protection and other intellectual
property rights in the development of agriculture
Role of patents and trade secrets

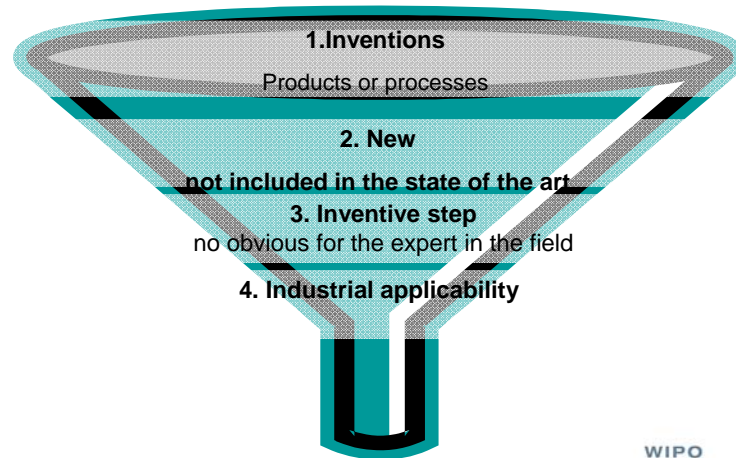
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Geneva, May 12, 2016

Main features of patent rights

- Right to *stop others* from making or selling the invention without a patent owner's consent
 - NOT a right to make or sell the invention
- Only available for *new* inventions in a field of *technology*
 - Need to fulfill conditions of patentability
- Geographically limited under *national* patent laws
 - but there are *regional* and *international* treaties
- Limited duration, *20 years* from filing date
- Annual renewal or maintenance *fees* (increasing with time)
- Some *limitations* to the rights
- *Property rights in inventions*
 - may be sold or licensed

The Patent System



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The international legal framework

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Paris Convention, 176 MS (few substantive obligations);
specialized agreements (Art. 19 Paris):

- PCT (1970, 148 CP); IPC (1971, 62 CP); Budapest Treaty (1977, 80 CP); PLT (2000, 38 CP)

WTO

TRIPS Agreement

- Minimum standards; enforcement of IPRs; WTO dispute settlement procedures

Regional agreements (e.g. EPO, EAPO, ARIPO, OAPI, GCC)

Preferential Trade Agreements (FTAs, EPAs)

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■ Patentable subject mater

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TRIPS Agreement Implementation: Art. 27

6



Explicit obligation to give protection

- Inventions - whether products or processes - in all fields of technology
- Micro-organisms



Explicit permission to exclude from patent protection

- Plants and animals
- Diagnostic, therapeutic and surgical methods



Implicit permission not to give protection

- Discoveries
- Substances existing in nature
- Incremental innovation

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■ Protection or exclusion from patentability of plants/Plants Varieties

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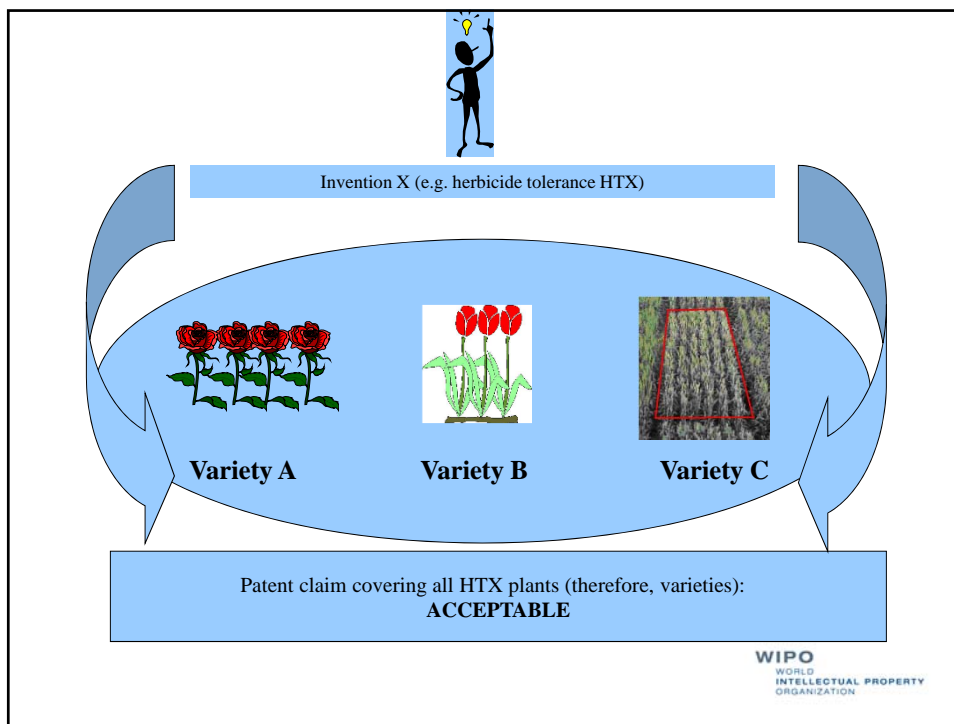
DIRECTIVE 98/44/EC

Article 4

1. The following shall not be patentable:

- (a) **plant** and animal **varieties**;
- (b) **essentially biological** processes for the production of plants or animals.

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Country	Provision of Law	Exclusions									
		Plants	Plant-Variety	Neither	Both	Animals	Animal-breeds	Neither	Both	Essentially-Biological-Processes	
Barbados	Section 11(1)(e) of the Patents Act No. 18, Cap. 314, of 26/07/2001	x	x	x	x	x	x	x	x	x	x
China	Article 25(4) of the Patent Law of 28/12/2008	x	x	x	x	x	x	x	x	x	x
Ghana	Section 2(e), (f) and (g) of the Patents Act, Act No. 657 of 2003	x	x	x	x	x	x	x	x	x	x
Japan	Act No. 122 of December 4, 2002, as last amended by Act No. 119 of July 16, 2003	x	x	x	x	x	x	x	x	x	x
Kenya	Sections 26(a) of <i>The Industrial Property Act, 2001</i>	x	x	x	x	x	x	x	x	x	x
Lao People's Democratic Republic	Section 21 of the Intellectual Property Law of 14/04/2008	x	x	x	x	x	x	x	x	x	x
Malaysia	Section 13(1)(b) of the Patents Act No. 291 of 1983 as last amended by Act No. 1264 of 2006	x	x	x	x	x	x	x	x	x	x
Mexico	Article 161) and V) of the Industrial Property Law of 25/06/1991 as last amended on 04/04/2012	x	x	x	x	x	x	x	x	x	x
Netherlands	Articles 1, 2a(1)(2)(c) and (d), and 3(1)(c) and (d) of the Patents Act of 15/12/1995 (Text as it applies on 03/06/2009)	x	x	x	x	x	x	x	x	x	x

Country	Provision of Law	Exclusion ^a								
		Plants	Plant Varieties	Neither	Both	Animals	Animal breeds	Neither	Both	Essentially Biological Processes
South Africa	Section 25(4)(b) of the Patents Act No. 37 of 1952 as last amended by Act No. 20 of 2005	☐	☑	☐	☐	☐	☑	☐	☐	☑
Spain	Articles 42) and 3) and 52) and 3) of the Law about Patents of Invention and Utility Models No. 11 of 20/03/1986 as last amended by Law No. Nº 14/2011, of 01/06/2011	☐	☑	☐	☐	☐	☑	☐	☐	☑
Trinidad and Tobago	Patents Act of 1996 as last amended by Act of 05/05/2000	☐	☐	☑	☐	☐	☐	☑	☐	☐
United Republic of Tanzania	Section 7(2)(b) of the Patents Act, Chapter 217 of 1995	☐	☑	☐	☐	☐	☑	☐	☐	☑
United States of America	Patent Law, 35 U.S.C. of 01/01/1953, 2007 version	☐	☐	☑	☐	☐	☐	☑	☐	☐
Vietnam	Article 59 5) and 6) of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005 as last amended by Order No. 12/2009/L-CTN of 29/06/2009	☐	☑	☐	☐	☐	☑	☐	☐	☑
European Union	Articles 2 and 4 of the Directive 98/44/EC of 6/07/1998 on the legal protection of biotechnological inventions	☐	☑	☐	☐	☐	☑	☐	☐	☑

■ Patentability of Substances existing in nature

Discovery

- ARMENIA: *Section 10 (1) (a) and (3) of the Industrial Property Law of 10/06/2008*

Article 10 .The Exception to Legal Protection (1) Within the meaning of Article 9 of this Law the following shall not be subject to legal protection: (a) scientific discoveries;

- BELARUS: *Article 2 (2) of the Law No. 160-Z on Patents for Inventions, Utility Models and Industrial Designs of 16/12/2002 as last amended on 29/10/2004*

2. (2) The following shall not be recognized as inventions:

- discoveries, scientific theories and mathematical methods;

Substances existing in nature

- INDIA: *Section 3 (c) and (j) of the Patent Act No. 39 of 1970 as last amended by Act No. 15 of 2005*

3. What are not inventions. The following are not inventions within the meaning of this Act:

c) the mere discovery of a scientific principle or the formulation of an abstract theory or **discovery of any living thing or non-living substance occurring in nature;**

- PAKISTAN: *Section 7 (2) (a) and (e) and (4) (b) of the Patent Ordinance No. LXI of 2000 as last amended by Patent Ordinance No. 2(1)/2002*

7.-(2) Subject to sub-section (3), the following shall not be regarded as invention within the meaning of sub-section (1), namely:- (e) substances that exist in nature or if isolated therefrom

Specific provisions allowing

- SLOVAKIA: *Articles 5 (2) and (3) (a) and 6 (1) (b) and (d) of the Patent Act No. 435/2001 as last amended by Act No. 202/2009 Coll.*

Article 5 Patentable subjects

(2) Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilised, including cases when invention relates to

- a) biological material which is **isolated from its natural environment** or is **produced by means of a technical process**, already occurred in a nature,
- d) an element **isolated from a human body** or **produced by other means of a technical process**, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element.

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Specific provisions excluding

- BRAZIL: *Sections 10 (I) and (IX) and 18 II of the Industrial Property Law No. 9.279 of 14/05/1996 (as last amended by Law No. 10.196, of 14/02/2001) and Article 31 of the Provisional measure No. 2.186-16*

10. The following are not considered to be inventions or utility models:

IX. all or part of natural living beings and biological materials found in nature, **even if isolated therefrom**, including the genome or germoplasm of any natural living being, and the natural biological processes.

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Case law. Association for Molecular Pathology v. USPTO and Myriad Genetics

- United States District Court (March, 2010): Isolated DNA is a “product of nature”
- Federal Circuit (July, 2011): Isolated DNA is patentable subject matter
- The Supreme Court: granted certiorari and remanded the case back to the Federal Circuit
- Federal Circuit maintained its decision
- The US Supreme Court (June 2013):

“A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.”

“Myriad did not create or alter either the genetic information encoded in the BCRA1 and BCRA2 genes or the genetic structure of the DNA. It found an important and useful gene, but groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”

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Gene sequences = patentable subject matter?

“An element **isolated** from the human body **or otherwise produced by means of a technical process**, including the sequence or partial sequence of a gene, may constitute a **patentable** invention, even if the structure of that element is identical to that of a natural element.”

(Article 5(2) EU-Directive)

The following are not considered to be inventions or utility models:
“all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.”

Law No. 9,279 of May 14, 1996
Section 10

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■ Scope of the exclusive rights

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Scope of protection

Biological materials self replicate

- Should the patent protection extend to future generations, if so, to which extent?
- Is special exhaustion regime required?
 - In traditional fields of technology - the patent owner's rights are "exhausted" in the sold item
 - In the field of biotechnology - is self-replication of the patented item considered "making" or "using"?

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CASE LAW

- Scope of protection in the USA *Bowman v. Monsanto*
Question presented to the Supreme Court:

Whether the Federal Circuit erred by refusing to find patent exhaustion in patented seeds even after an authorized sale

Supreme Court (May 2013): “Patent exhaustion does not permit a farmer to reproduce patented seeds through planting and harvesting without the patent holder’s permission

- In Europe: *Monsanto v. Cefetra*

Dutch court referred the following question to the European Court of Justice:
Should Article 9 of the Biotech Directive be understood in such a way that it confers protection when the genetic information present in the material does not perform any function but has performed a function in the past or when it is theoretically capable of performing a function in the future (ie. when the gene sequence is isolated and again introduced in plant cells)?

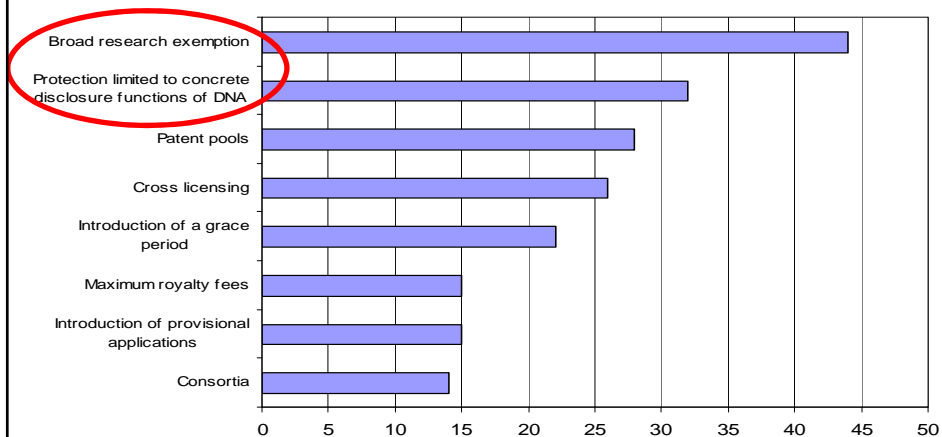
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Monsanto v. Cefetra CJEU’s Decision (July, 2010)

- Art 9 Biotech Directive requires that the DNA sequence performs its function in the material in which it is incorporated (present)
- According to Art 9 Biotech Directive , protection **is not available** if the genetic information has ceased to perform its function (past)
- Following from Art 9 Biotech Directive, protection **is also not available** if it **possibly** perform its function again (future)
- Different case if genetic material is **actually** inserted in different biological material and performs its function

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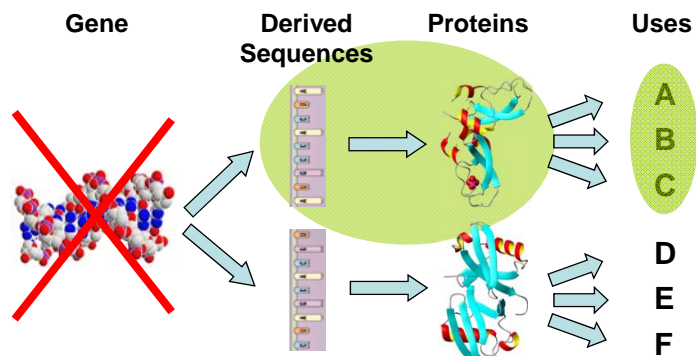
Possible remedies within the IP system to solve the tension caused by the protection



CH Survey: 8.2 Remedies, Fig. 35 (named as many times as effectively to ...)
<http://www.ige.ch/E/jurinfo/documents/j10005e.pdf>

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The approach of the Swiss Patent Law



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Protection of undisclosed information

Ex. manufacturing processes, sales methods, distribution methods, consumer profiles, advertising strategies, lists of suppliers and clients

Criteria

- The information must be secret
- It must have commercial value because it is a secret
- It must have been subject to reasonable steps by the rightful holder of the information to keep it secret

Prevent unauthorized use of protected undisclosed information

Protection of undisclosed information - comparison with patent protection -

Potential advantage

- No time limit
- No registration required
- Immediate effect
- Commercial information can be protected

Potential disadvantage

- Possibility of reverse engineering
- May be patented by an independent third party
- Once the information is made public, secrecy is lost
- Difficult to enforce

Thank you !

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