

Patents: What is it all about?

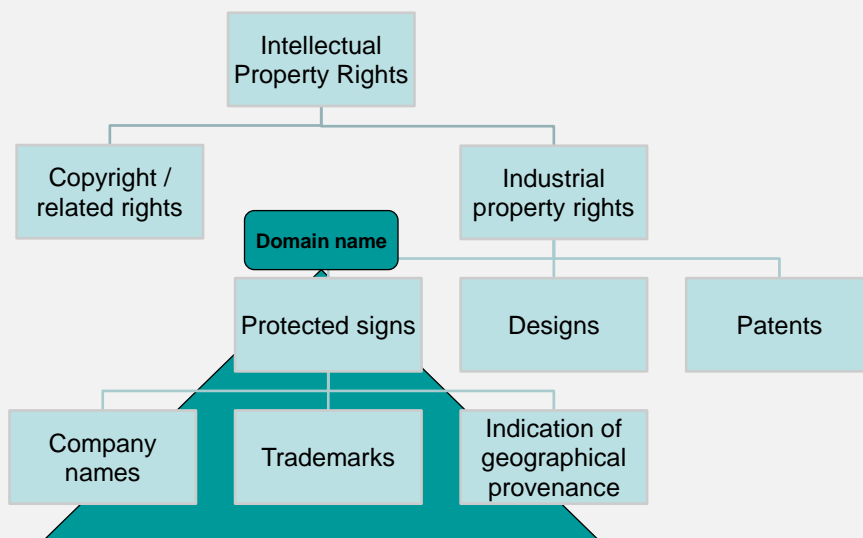
**Patenting in Life Sciences:
a hands on workshop
Murten, June 11/12, 2012**

**Heinz Mueller
Swiss Federal Institute of Intellectual
Property
University of Basel**

04.06.2012

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Protective Rights System

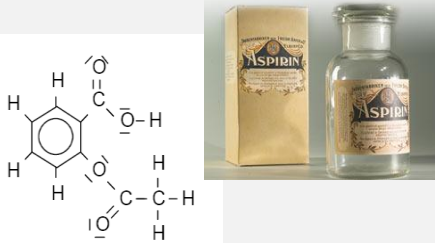
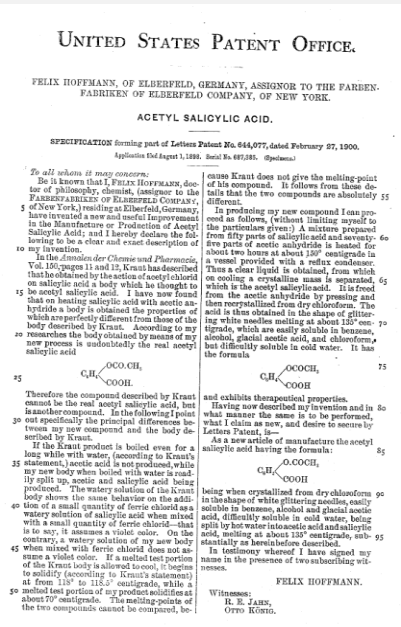


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Acetyl salicylic acid



registered trademark since 1899



Aspirin is synthesized by acetylation of sialicylic acid – obtained from the bark of the willow tree

Sales today for Bayer:
ca. 6-800 m Euro p.a.

Patents



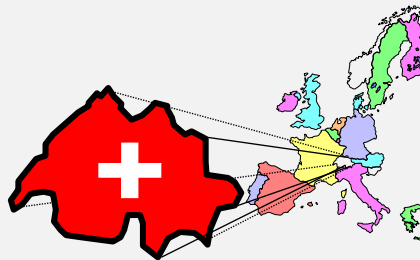
A Patent is a Right for its Owner
to **Exclude Thirds** from a **Commercial Exploitation**
of the Invention.

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Principle of territoriality

protection **only** in
the country or
region where you
claim it



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All patent documents are **published, worldwide**



In most countries, patent applications are published 18 months after filing and granted patents after granting

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Patents are not a “license” to use (sell) the invention

A patent is **not a permission to use** an invention (not a marketing authorization).



A patent is **not a seal of approval for an invention or its quality.**



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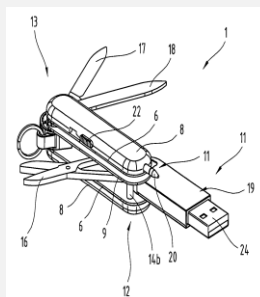
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General Rules for Patentability of an Invention

- **Invention**
- **Novelty**
- **Commercial Use**
- **Disclosure**
- **Reproducibility**
(by a specialist in the field)



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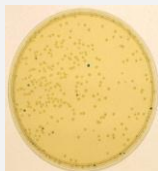
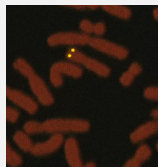


General Requirements for Obtaining a Patent

Technical Solution for a Technical Problem

(US: "Anything under the sun that is made by man.")

	Novelty	Inventive	Industrial Application	
CH	§ 1(1)	§ 1(2)	1(1)	
EPC	§ 54(1)	§ 56(1)	§ 57	
USC 35	§ 101	(non-obvious § 103)	(utility § 101)	



Disclosure, Reproducibility (by a specialist in the field)

Swiss Federal Institute of Intellectual Property

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What is an invention?

An invention **solves a technical problem** with technical means.



"Anything under the sun made by man."



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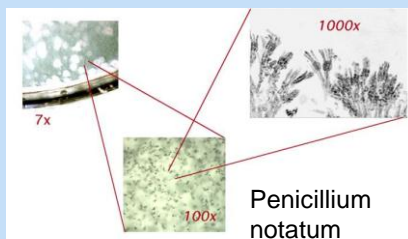
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What is an invention?

Discovery

= Description of something existing

= Extension of human **knowledge**

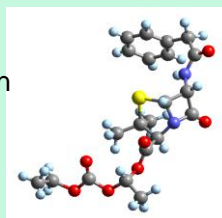


Invention

= Instruction how to solve a problem with technical means

= Extension of human **abilities**

Penicillin



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Novelty

- Published patents and patent applications
- **Scientific papers**
- **Newspaper articles**
- **Flyers**
- Radio or TV broadcastings
- **Public presentations**
- Photographs
- **Internet**



Can biological material be novel?



According to Article 54 of the EPC, an invention shall be considered novel if it does not form part of the state of the art.

Biological material in its natural state is not available to the public and thus not part of the prior art. It is a new product, because it was not previously available to the public.



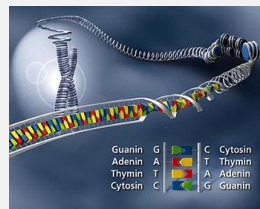
Rule 27

Patentable biotechnological inventions

Art. 52

Biotechnological inventions shall also be patentable if they concern:

(a) **biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;**



Art. 1b

III. Genetic sequences



1 A naturally occurring sequence or partial sequence of a gene is not patentable as such.

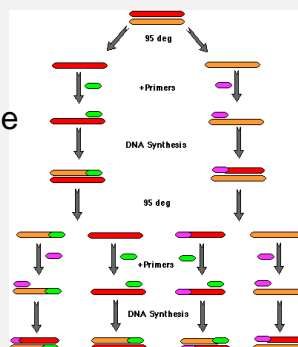
2 Sequences that are derived from a naturally occurring sequence or partial sequence of a gene, may however be patented as an invention, if they are produced by a technical process, their function is specifically indicated, and the further requirements of Article 1 are fulfilled; Article 2 is reserved.

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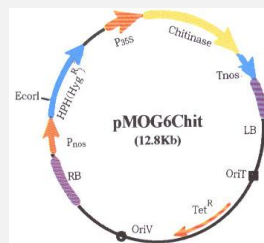
Polymerase Chain Reaction



- Art. 8c
- IV. Nucleotide sequences
- The protection conferred by a right to a nucleotide sequence that is derived from a naturally occurring sequence or partial sequence of a gene is **limited to the sequence segments that perform the function specifically described in the patent.**

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- Art. 8b
- III. Genetic information
- If the invention relates to a product that consists of or contains genetic information, the protection conferred by the patent extends to any material in which the product is incorporated and in which the genetic information is contained and performs its function. Article 1a paragraph 1 is reserved.

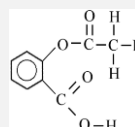
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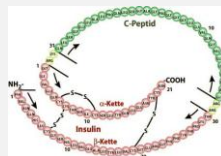
Protection of a biological or chemical compound

▪ compound

(Aspirin)
 acetylsalicylic acid



Human recombinant
 insulin



- Additional characteristics
 melting point 135,0°C, boiling point 140,0°C
 Mechanism of function, potency
- Industrial Application (intended purpose)
 acetylsalicylic acid can be used as an analgesic
 insulin can be used to treat diabetes

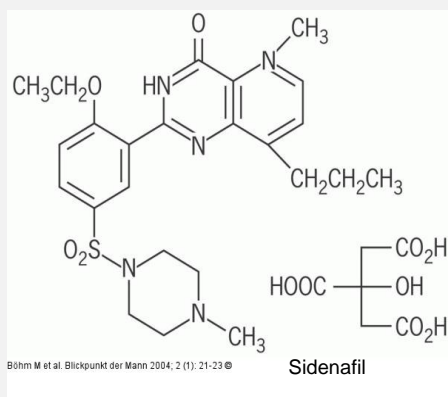
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Absolut compound protection

Chemical compounds

The chemical compound is protected for all uses, including the uses not known at the application date.



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..and biological compounds?

- **Proteins:** Absolute compound protection
- **Nucleotide sequences:** Absolute compound protection
 But: the protection is limited to the sequence segments that perform the function specifically described in the patent.

→ **Second medical indications possible for both**

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2nd Medical Indication



Known Indication

reduction of inflammation,
analgesia (relief of pain)

New Indication

irreversible inactivation
of cyclooxygenase (COX),
prevention of blood clotting

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Industrial Application



The description should indicate explicitly the way in which the invention is capable of **exploitation in industry**, if this is not obvious from the description or from the nature of the invention.

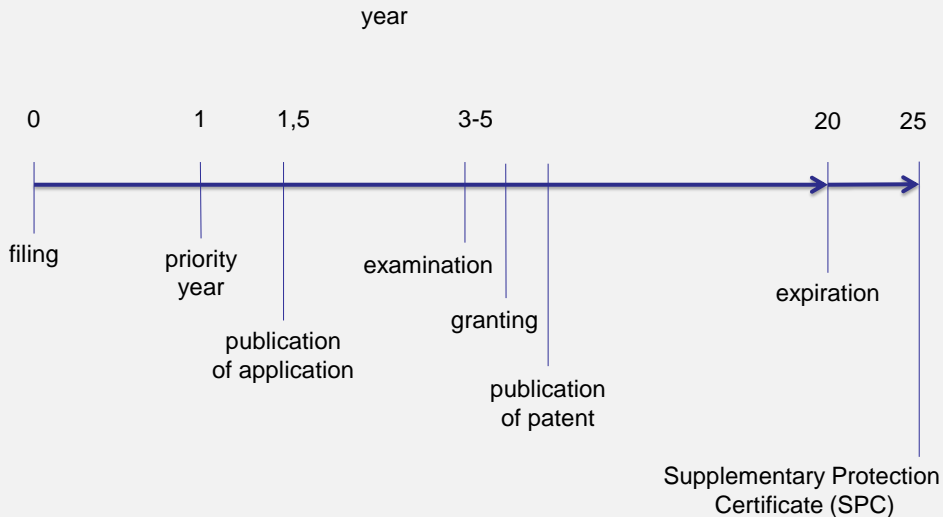
Also, in relation to certain biotechnological inventions, i.e. **sequences and partial sequences of genes, the industrial application is not self-evident**. The industrial application of such sequences must be disclosed in the patent application.

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the life of a patent



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Supplementary Protection Certificate (SPC) for pharmaceuticals and pesticides



Protection

Up to + 5 years

Requirements

- Patent must be in force
- Active substance must be approved for sale (Swissmedic, BVet, BLW).

Formalities

Examination
Annual fees

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What can be patented?



What: **Product**

What for: **Use**

How: **Process**

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The „no invention“ argument

„Plants and animals are not inventions of a pharma corporation. It should not be allowed to patent them similar to chemicals or technical products.“



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Plant and animal varieties



1. The following shall not be patentable:
 - (a) plant and animal varieties;
 - (b) essentially biological processes for the production of plants or animals (breeding, crossing).
2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

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Patenting of Microorganisms (MO)

Definition of MO:

In general single cell organisms not visible by the naked eye that can be proliferated and manipulated in the lab.

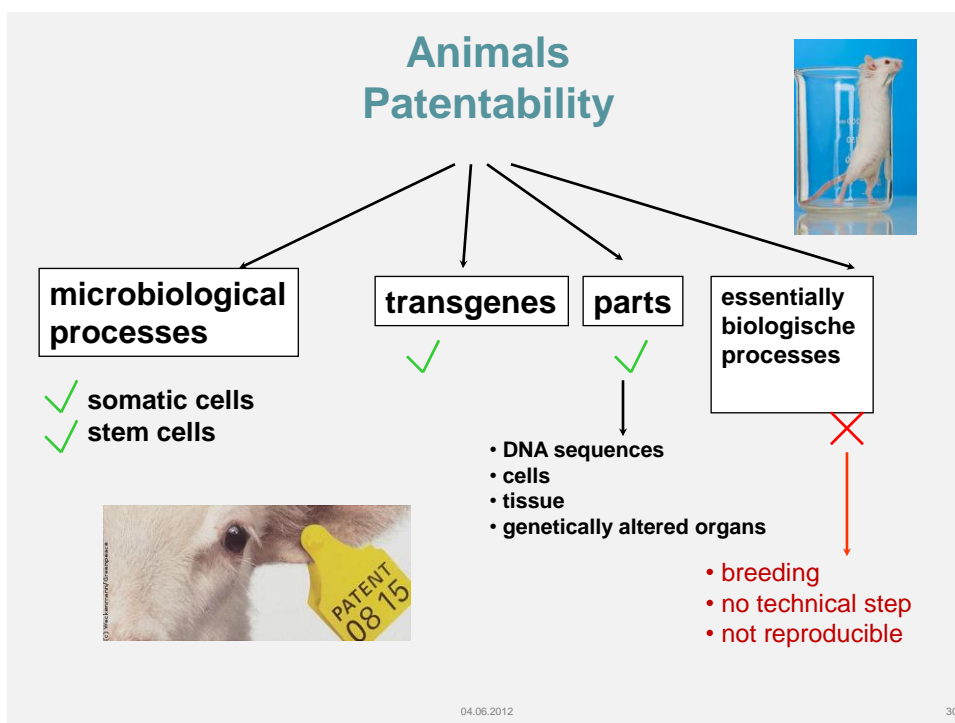
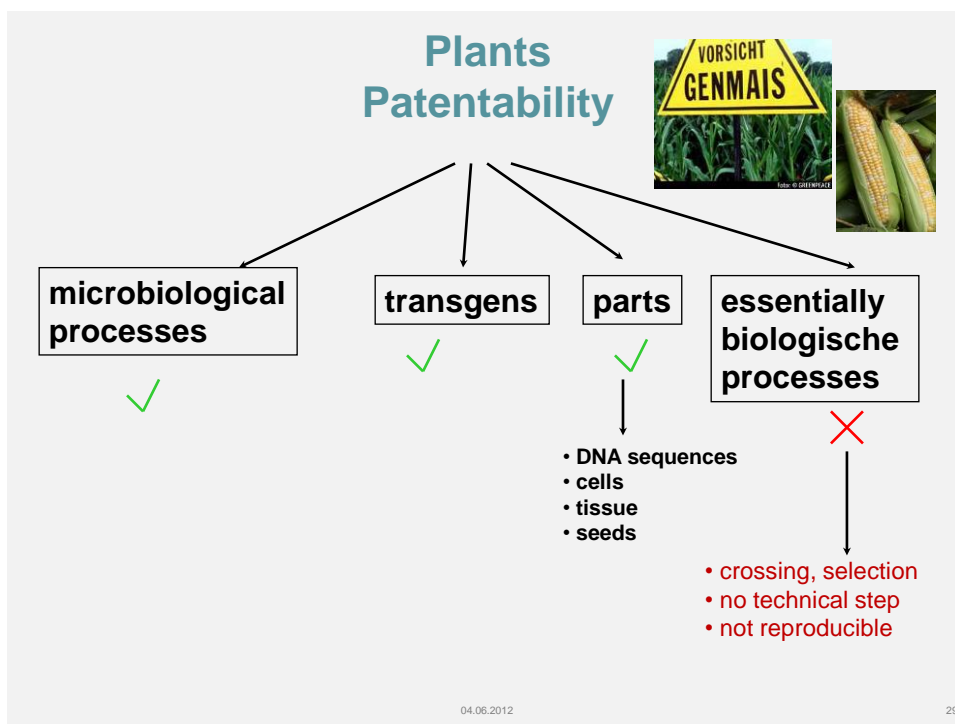


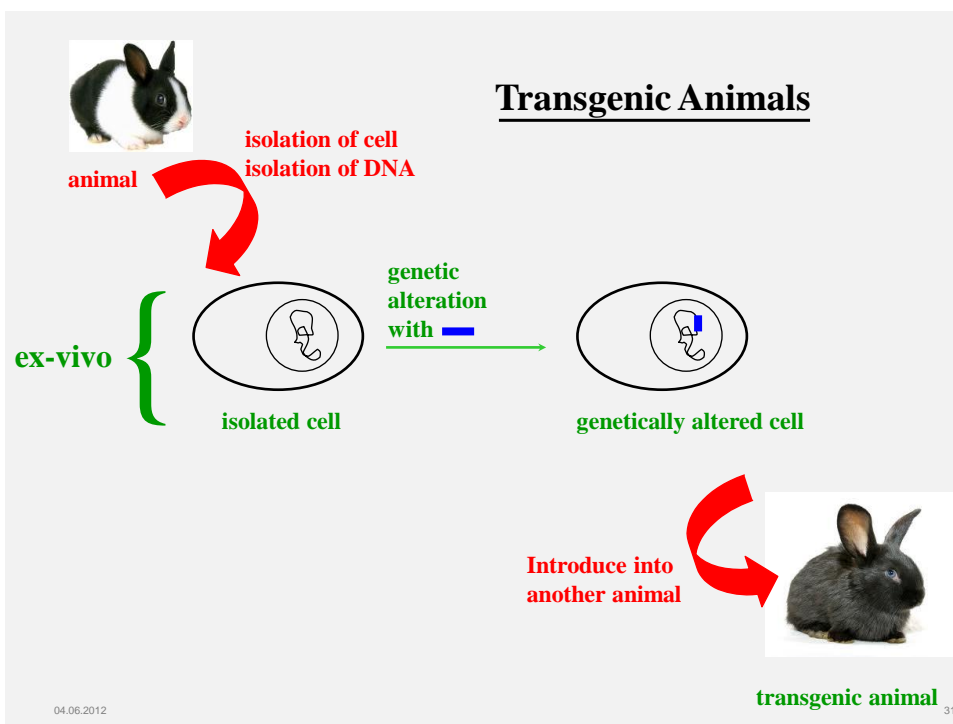
- bacteria, yeast, fungi, algae, and protozoa
- plasmids and viruses
- human, animal or plant cells

Microorganisms are patentable if they are isolated from its natural environment or produced by means of a technical process

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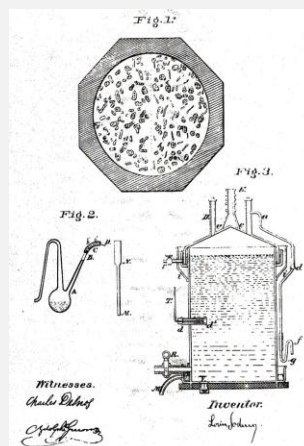
“Patents on life”

US141072 : Manufacture of Beer and Yeast Louis Pasteur Patented July 22, 1873

I claim—

1. The method of obtaining pure yeast by eliminating the organic germs of disease from brewers' yeast, in the manner described.
2. Yeast, free from organic germs of disease, as an article of manufacture.
3. The vessel, having neck A B, rubber tube b' c', and glass plug O D, as and for the purpose described.
4. The apparatus, consisting essentially of a covered vessel having water-trough around the top, rubber tube a d, metal pipe a, tube d f g, top and bottom gutters, and pipes D E, together with suitable cocks, thermometer, outlets, and inlets, substantially as set forth.

LOUIS PASTEUR.



The patentability of human beings



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Exclusions from Patentability

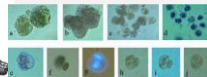
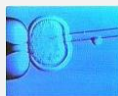
Art. 1a

II. The human body and its elements

- 1 **The human body as such in all stages of its formation and development, including the embryo, is not patentable.**
- 2 Elements of the human body in their natural environment are not patentable. An element of the human body is however patentable as an invention if it is produced by means of a technical process, a beneficial technical effect is indicated and the further requirements of Article 1 are fulfilled; Article 2 is reserved.

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Art. 2

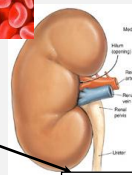
B. Exclusion from patentability

- 1 Inventions whose exploitation is **contrary to human dignity** or that disregard the dignity of the creature or that are in any other way contrary to public convention or morality are excluded from patentability. In particular, no patent may be granted for:
 - a. processes for **cloning human beings** and the clones obtained thereby;
 - b. processes for forming **hybrid organisms by using human germ cells**, human totipotent cells or human embryonic stem cells and the entities obtained thereby;
 - c. processes of **parthenogenesis using human germ cells** and the parthenotes produced thereby;
 - d. processes for **modifying the germline identity of human beings** and the germline cells obtained thereby;
 - e. unmodified **human embryonic stem cells** and stem cell lines;
 - f. the **use of human embryos** for non-medical purposes;
 - g. processes for **modifying the genetic identity of animals that are likely to cause suffering** without being justified by reason of overriding interests that are worthy of protection, as well as the animals resulting from such processes.

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Human parts Patentability



Microbiological processes

- ✓ Somatic cells
- ✓ Stem cells
- ✓ Embryonic cells
- ✓ Germline cells

Genetic Alterations

- ✓ Somatic cells
- ✓ Stem cells
- ? Embr. Stem cells
- ✗ Germline cells

Parts

- ✓ Derivatives of DNA sequences
- ✓ Organs
- ✓ Blood
- ✓ Tissue
- ✓ Cells

Therapy, Diagnostics Surgical procedures



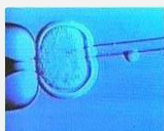
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Exclusions from Patentability

- **Inventions contrary to Ordre Public or Morality**



- **Processes of surgery, therapy and diagnostics on the human or animal body**



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Traditional Knowledge and genetic resources



- **Art. 49a**
- **1** The patent application must contain information on the source:
 - a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource;
 - b. of **traditional knowledge of indigenous or local communities of genetic resources** to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge.

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Disclosure

Protection titles as source of information

- the inventor must disclose **all** that he/she knows about the invention in the patent application
- the patent is **published** worldwide (internet)

Information in return of the commercialisation monopoly

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The flood of information...



- every 20 seconds a patent document is published around the world
- 1.6 Million per year
- Today approx. 70'000'000 patent documents
- ~5 Million in force

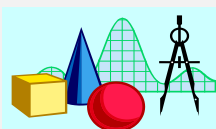
Up to 80% of all technical knowledge is published only in patent applications

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Why searches?



technical

**Technical solutions of
technical problems
Technology trends**



legal

**Avoid infringement
Legal status
defence**



economical

**F+E investment
Competitors
Market Trends
Licences**

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Important freely available patent databases (non commercial)

- **Swissreg:** Database of the IGE (Search language: german, french, italien, english)
<http://www.swissreg.ch>
- **Espacenet:** Database of the European Patent Office (Search language: english)
<http://worldwide.espacenet.com>
- **Depatisnet:** Datenbase of the German Patent Office (Search language: german)
<http://www.depatistnet.de>
- **US Patent and Trademark Office:** Database of the US Patent Office
www.uspto.gov/patft

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Assisted Patent Searches for Public Research Institutions

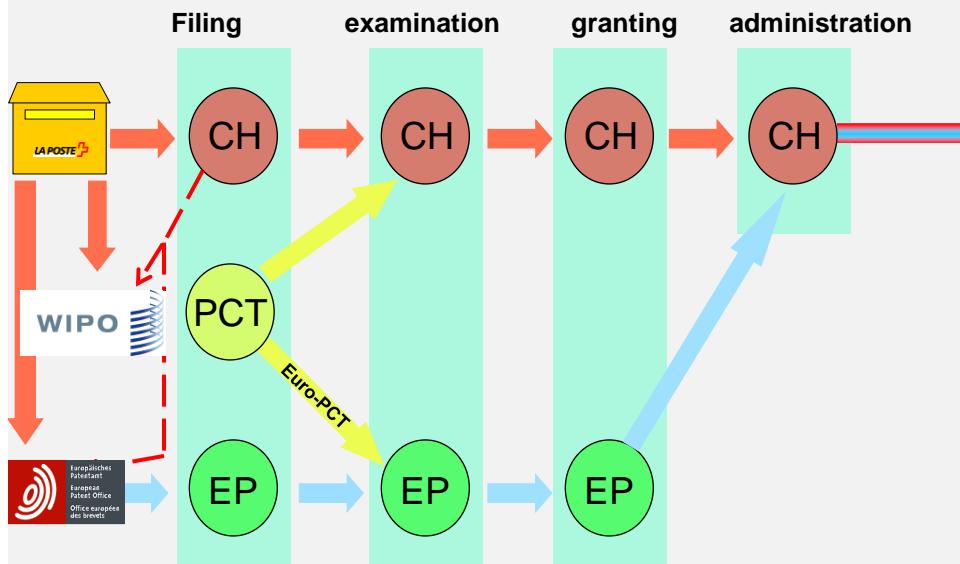


- **The customer (researcher) must be personally present** at the Institute for the search.
- The **time limit** for the Assisted Patent Search is one day, including the informational section.
- The search is done **in all accessible patent databases including EPODOC**, the European Patent Office database.
- **Price: CHF 300.- (Euro 200.-) for one full day**

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3 application routes



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US Provisional Application

- Its only statutory requirement is that it **discloses your invention** in sufficient detail that anyone skilled in the applicable art can *make* and *use* the invention. (**no claims necessary**) There are **no format requirements** on either the text or drawings. The provisional application can be filed with the Patent Office for **\$75** and will buy you *one year* of protection. Within that year you must either file a *formal* US patent application (or US PCT application) or abandon the idea.
- It might be possible to use the provisional application as a priority application in countries other than the US. (EPA ABI 1996 81, PMMBI 1996 39)

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Disadvantages of US Provisional Applications

- Provisional applications are **not examined** on their merits.
- Provisional applications **cannot claim the benefit of a previously-filed application**, either foreign or domestic.
- It is recommended that the disclosure of the invention in the provisional application be **as complete as possible**.

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One-year grace period in the United States



- An application for a U.S. patent must be filed **no later than 1 year after the earliest date on which the invention was disclosed** in writing anywhere in the world to the public (such as in a paper delivered at a scientific conference or an article published in a journal); or the invention was offered for sale in the United States, such as by providing a nonconfidential sampling to another party; or the invention was actually sold in the United States.
- If the inventor fails to file a U.S. application within that 1-year period (**known as the grace period**), the public disclosure, the offer for sale, or the sale of the invention prevents a valid patent from being issued to the inventor for that invention.
- The one-year grace period is also available for a U.S. patent application which claims priority based on an earlier filed foreign patent application, in which case the foreign application must be filed within the one-year grace period. **However, there is no similar grace period available for patent applications in most other countries. Thus, disclosure before the application will bar the right to a patent outside the US.**

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Who owns the patent?

- Applicant(s)
or his/her legal predecessor(s)
- If “work for hire”: Company (assignee)



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ETH PATENT POLICY



- 1/3 for the inventor
- 1/3 for free research of the respective institute
- 1/3 for ETH for research and the technology transfer

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Eidgenössisches Institut für Geistiges Eigentum
Institut Fédéral de la Propriété Intellectuelle
Istituto Federale della Proprietà Intellettuale
Swiss Federal Institute of Intellectual Property

I'm still confused...



... but on a much higher level!

**Heinz Mueller: heinz.mueller@ige.ch
www.ige.ch**

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Intellectual Property