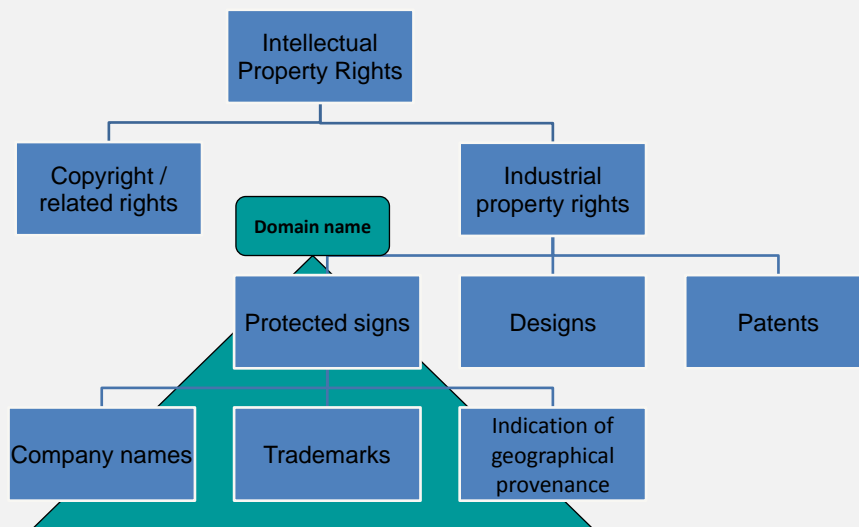


Patents: What is it all about?

Murten, June 23/24, 2014

Heinz Mueller
Swiss Federal Institute of Intellectual Property, Berne
University of Basel

Protective Rights System





Acetyl salicylic acid



registered trademark since 1899



UNITED STATES PATENT OFFICE.

FELIX HOFFMANN, OF ELBERFELD, GERMANY, ASSIGNOR TO THE FARBEN-
FABRIKEN OF ELBERFELD COMPANY, OF NEW YORK.

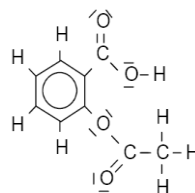
ACETYL SALICYLIC ACID.

SPECIFICATION forming part of Letters Patent No. 646,077, dated February 27, 1900.
Application filed August 1, 1898. Serial No. 492,585. *Discontinued.*

To all whom it may concern:
Be it known that I, FELIX HOFFMANN, do hereby certify that the following is a true and correct description of the invention of FELIX HOFFMANN, of Elberfeld, Germany, in the manufacture of Acetyl Salicylic Acid, and I hereby declare the following to be a clear and exact description of my invention.
In the *Annalen der Chemie und Pharmacie*, Vol. 150, pages 11 and 12, Krat has described that he obtained by the action of acetyl chloride on salicylic acid a body which he thought to be acetyl salicylic acid. I have now found that on heating salicylic acid with acetic anhydride a body is obtained the properties of which are perfectly different from those of the body described by Krat. According to my researches the body obtained by means of my new process is undoubtedly the real acetyl salicylic acid.
It is known that I, FELIX HOFFMANN, do hereby certify that the following is a true and correct description of the invention of FELIX HOFFMANN, of Elberfeld, Germany, in the manufacture of Acetyl Salicylic Acid, and I hereby declare the following to be a clear and exact description of my invention.
In the *Annalen der Chemie und Pharmacie*, Vol. 150, pages 11 and 12, Krat has described that he obtained by the action of acetyl chloride on salicylic acid a body which he thought to be acetyl salicylic acid. I have now found that on heating salicylic acid with acetic anhydride a body is obtained the properties of which are perfectly different from those of the body described by Krat. According to my researches the body obtained by means of my new process is undoubtedly the real acetyl salicylic acid.
The compound described by Krat cannot be the real acetyl salicylic acid, but is another compound. In the following I point out specifically the principal differences between my new compound and the body described by Krat.
If the Krat product is boiled even for a long while with water, (according to Krat's statement), acetic acid is not produced, while my new body when boiled with water is readily split up, acetic and salicylic acid being produced. The watery solution of the Krat body shows the same behavior on the addition of a small quantity of ferric chloride as a watery solution of salicylic acid when mixed with a small quantity of ferric chloride—that is to say, it assumes a violet color. On the contrary, a watery solution of my new compound when mixed with ferric chloride does not assume a violet color. If a small test portion of the Krat body is allowed to cool, it begins to solidify (according to Krat's statement) at from 118° to 118.5° centigrade, while a small test portion of my product solidifies at about 70° centigrade. The melting-points of the two compounds cannot be compared, because Krat does not give the melting-point of his compound. It follows from these details that the two compounds are absolutely different.
In producing my new compound I can proceed as follows, (without limiting myself to the particular given.) A mixture prepared from fifty parts of salicylic acid and seventy-five parts of acetic anhydride is heated for about two hours at about 135° centigrade in a vessel provided with a reflux condenser. Then a clear liquid is obtained, from which on cooling a crystalline mass is separated, which is the acetyl salicylic acid. It is freed from the acetic anhydride by pressing and acid is thus obtained in the shape of glittering white needles melting at about 135° centigrade, which are easily soluble in benzene, alcohol, glacial acetic acid, and chloroform, but difficultly soluble in cold water. It has the formula
$$\text{C}_6\text{H}_4 \begin{array}{l} \text{COOCH}_3 \\ \text{COOH} \end{array}$$

and exhibits the following properties.
Having now described my invention and in what manner the same is to be performed, what I claim as new, and desire to secure by Letters Patent, is—
As a new article of manufacture the acetyl salicylic acid having the formula:
$$\text{C}_6\text{H}_4 \begin{array}{l} \text{COOCH}_3 \\ \text{COOH} \end{array}$$

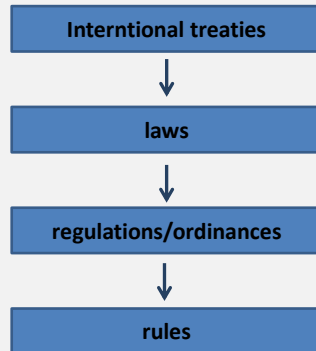
being when crystallized from dry chloroform in the shape of white glittering needles, easily soluble in benzene, alcohol and glacial acetic acid, difficultly soluble in cold water, being split up by hot water into acetic acid and salicylic acid, melting at about 135° centigrade, substantially as hereinafter described.
In testimony whereof I have signed my name in the presence of two subscribing witnesses.
FELIX HOFFMANN.
Witnesses:
H. B. JAMES,
OTTO KUNIG.



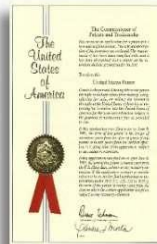
Aspirin is synthesized by acetylation of salicylic acid – obtained from the bark of the willow tree

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

The patent protection rights are internationally harmonized by **treaties** and based on **laws**, **regulations** and **rules**.



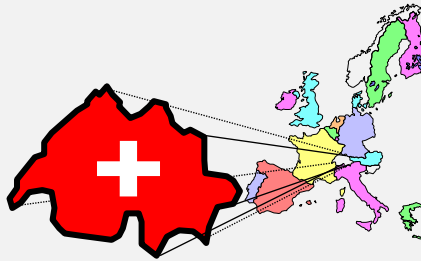
Patents



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

Principle of territoriality

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

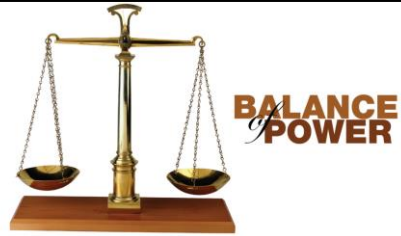


Keep the patent secret?

All patent documents are **published, worldwide**



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



Disclosure

In return to the exclusive right

- the inventor must disclose all that he/she knows about the invention in the patent application
- the patent application and the patent are published (patent applications in general 18 months after filing)

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

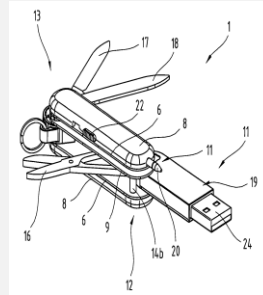


A patent is **not a seal of approval for an invention or its quality.**



General Rules for Patentability of an Invention




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

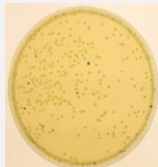
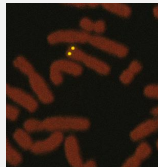


General Requirements for Obtaining a Patent

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)

What is an invention?

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



"Anything under the sun **made by man**."



United States Patent [19]

Iwasa et al.

[11] Patent Number: 4,807,078

[45] Date of Patent: Feb. 21, 1989

[54] FLEXIBLE DISK JACKET COLORED
WITHIN SPECIFIC MUNSELL RANGES

[75] Inventors: Masakazu Iwasa; Kazuhiko Morita,
both of Odawara, Japan

[73] Assignee: Fuji Photo Film Co., Ltd., Japan

[21] Appl. No.: 143,247

[22] Filed: Jan. 4, 1988

Related U.S. Application Data

[63] Continuation of Ser. No. 669,320, Nov. 7, 1984, abandoned.

[30] Foreign Application Priority Data
Nov. 11, 1983 [JP] Japan 58-212219

[51] Int. Cl. G11B 23/03

[52] U.S. Cl. 360/133

[58] Field of Search 360/133, 132; 206/444,
206/312-313

References Cited U.S. PATENT DOCUMENTS

4,352,132 9/1982 Gyl 360/133 X
4,400,753 8/1983 Beebe et al. 360/133
4,413,298 11/1983 Pecosk et al. 360/133
4,485,421 11/1984 Hoshino 360/133

OTHER PUBLICATIONS

"Strategic Systems Corporation", BYTE Publications,
Inc., Sep. 1983, vol. 8, No. 9, p. 160.

Primary Examiner—Stuart N. Hecker
Assistant Examiner—David J. Severin
Attorney, Agent, or Firm—Pasquale A. Razzano

ABSTRACT

[57] A flexible disk jacket
disk-like magnetic reco-
form a flexible disk is fo
into a bag-like shape. TI
color having a Munsell

3 Claims

We claim:

1. A flexible disk jacket for accommodating therein a magnetic recording medium to form a flexible disk formed by folding a plastic sheet into a bag-like shape characterized in that at least substantially the entire outer surface of the plastic sheet itself is colored in a chromatic color having a Munsell chroma in the range of 4-10, a Munsell hue in the range of 2.5-5 and a Munsell value in the range of 4-8.

2. A flexible disk jacket as defined in claim 1 in which said outer surface of the plastic sheet is matted.

3. A flexible disk jacket as defined in claim 1 in which at least one pigment selected from the group consisting of yellow-orange pigments, red pigments, blue-green violet pigments and white pigments is used for coloring said plastic sheet.

* * * * *

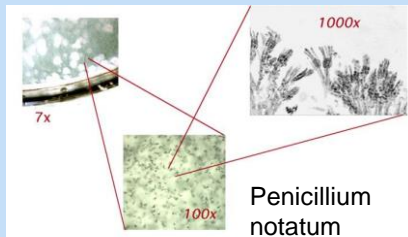
EPO: „aesthetic creation“
→ not patentable

What is an invention?

Discovery

= Description of something existing

= Extension of human **knowledge**

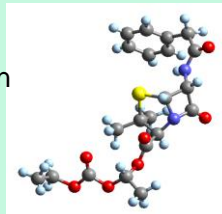


Invention

= Instruction how to solve a problem with technical means

= Extension of human **abilities**

Penicillin



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.

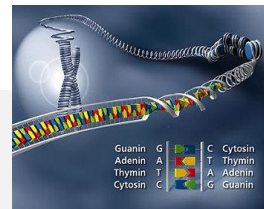
Rule 27

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

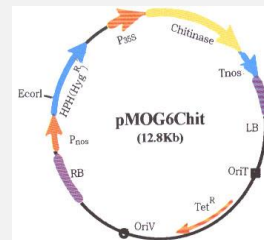


- 1 **A naturally occurring sequence or partial sequence of a gene is not patentable as such.**
- 2 Sequences that are derived from a naturally occurring sequence or partial sequence of a gene, may however be patented as an invention, if they are produced by a technical process, their function is specifically indicated, and the further requirements of Article 1 are fulfilled; Article 2 is reserved.



The diagram illustrates the exponential amplification of DNA fragments through PCR. It starts with a single DNA fragment (red and green segments). The process involves three main steps: denaturation (95 deg), primer binding (+Primers), and DNA synthesis. This cycle repeats, showing how a single fragment can be amplified into multiple copies.

- 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.**

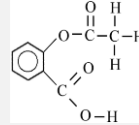


- Art. 8b
- III. Genetic information
- If the invention relates to a product that consists of or contains genetic information, the protection conferred by the patent extends to any material in which the product is incorporated and in which the genetic information is contained and performs its function.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

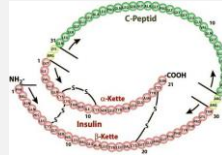
Protection of a biological or chemical compound

- Compound

(Aspirin)
acetylsalicylic acid



Human recombinant
insulin



- Additional characteristics

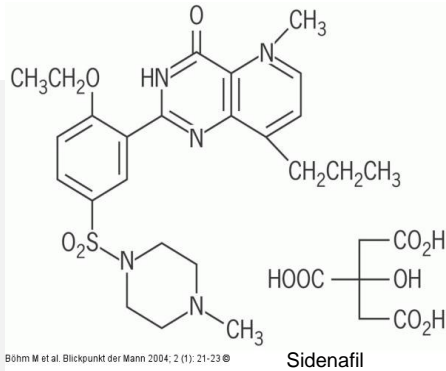
melting point 135,0°C, boiling point 140,0°C
Mechanism of function, potency

- Industrial Application (intended purpose)

acetylsalicylic acid can be used as an analgesic
insulin can be used to treat diabetes

Absolut compound protection

Chemical compounds



Böhm M et al. Blickpunkt der Mann 2004; 2 (1): 21-23 ©

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



..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**

2nd Medical Indication



Known Indication

reduction of inflammation,
analgesia (relief of pain)

New Indication

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

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.

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

What can be patented?



What: **Product**

What for: **Use**

How: **Process**

17.06.2014

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.“



Plant and animal varieties

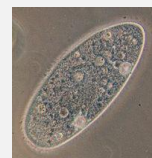


1. The following **shall not be patentable**:
 - (a) plant and animal varieties;
 - (b) essentially biological processes for the production of plants or animals (breeding, crossing).
2. Inventions which concern plants or animals **shall be patentable** if the technical feasibility of the invention is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

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

Plants Patentability



microbiological
processes



transgens



parts



- DNA sequences
- cells
- tissue
- seeds

essentially
biologische
processes



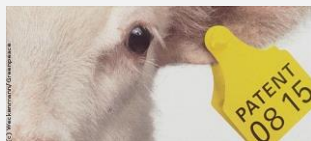
- crossing, selection
- no technical step
- not reproducible

Animals Patentability



microbiological
processes

- ✓ somatic cells
- ✓ stem cells



transgenes



parts

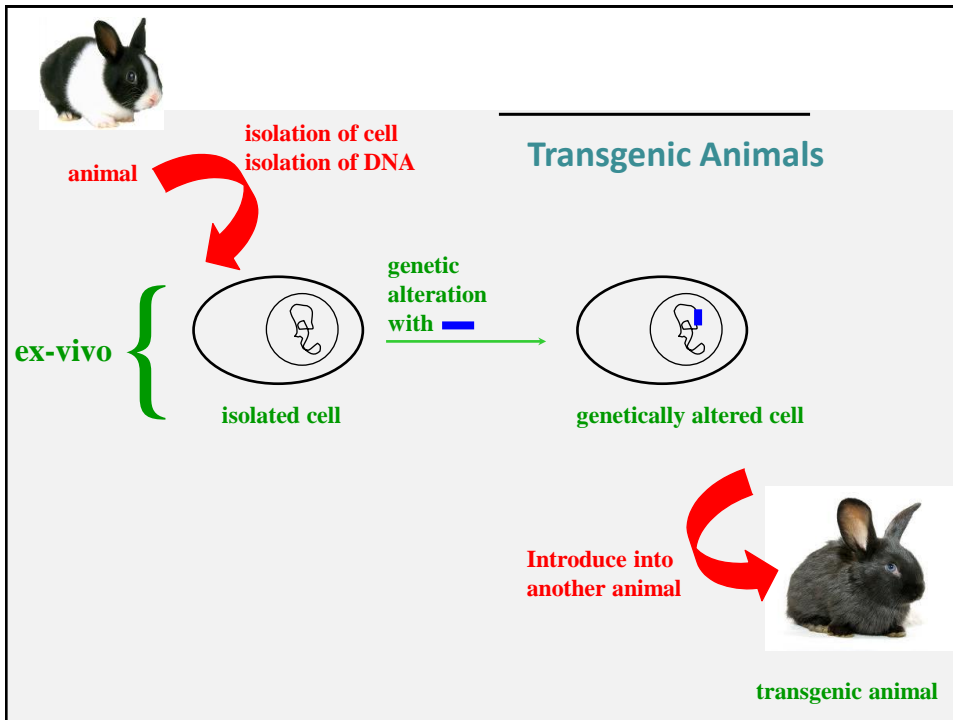


- DNA sequences
- cells
- tissue
- genetically altered organs

essentially
biologische
processes



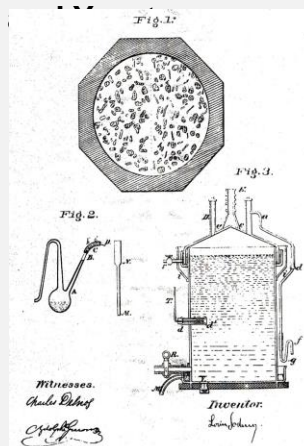
- breeding
- no technical step
- not reproducible



“Patents on life”

US141072 : Manufacture of Beer
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

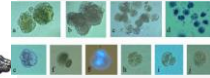
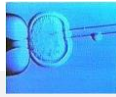


Exclusions from Patentability

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.



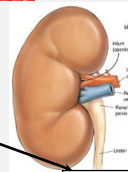
Art. 2

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.



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

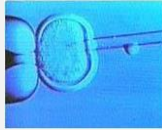
- ✓ Derivatives of DNA sequences
- ✓ Organs
- ✓ Blood
- ✓ Tissue
- ✓ Cells

Therapy, Diagnostics Surgical procedures



Exclusions from Patentability

- Inventions contrary to Ordre Public or Morality



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



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.

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**

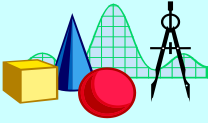
The flood of information...



- **every 14 seconds** a patent or utility model is filed somewhere in the world
- 2.2 millions per year
- approx. **80'000'000 patent** documents in the databases
- ~5 millions in force


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

Why searches?

technical

Technical solutions of technical problems
Technology trends



legal

Avoid infringement
Legal status
defence



economical

F+E investment
Competitors
Market Trends
Licences

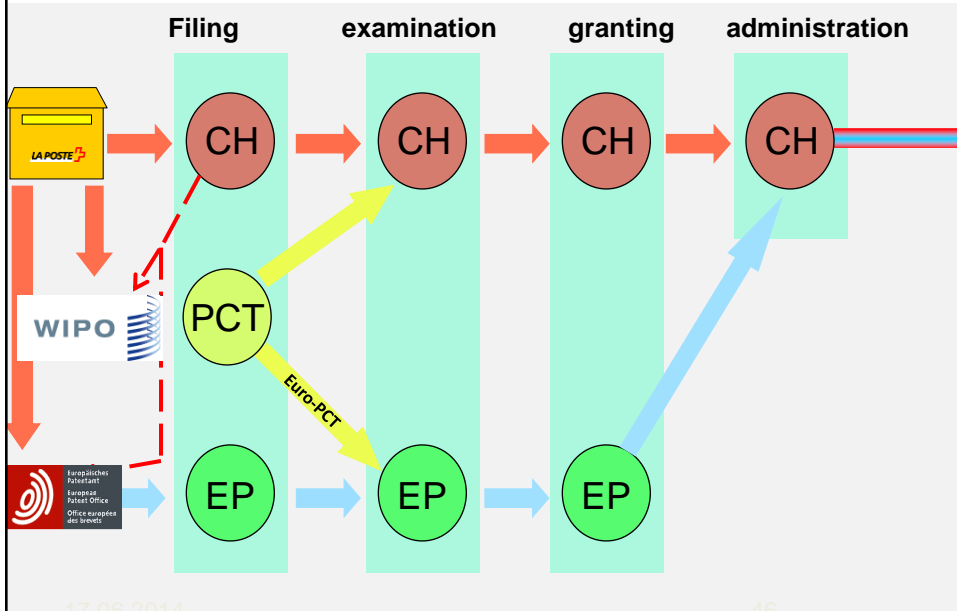
Important freely available patent databases (non commercial)

- 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: Databse 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

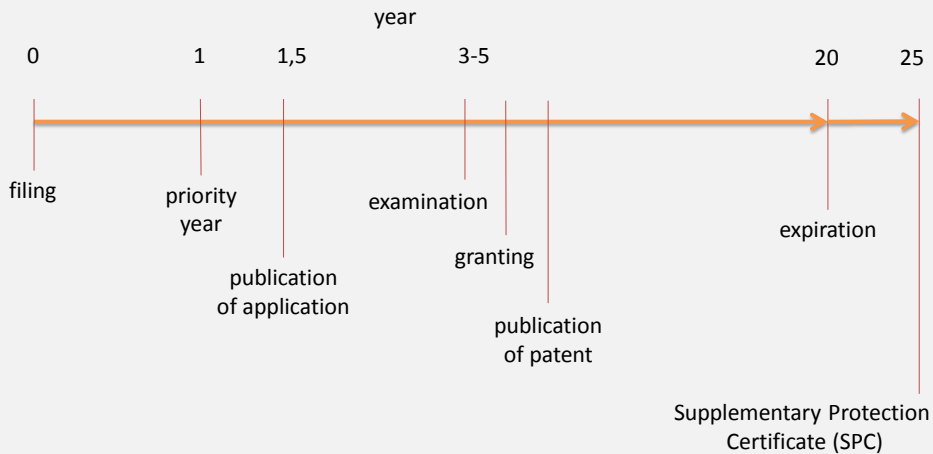
Assisted Patent Searches for Public Research Institutions

- **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**

3 application routes



the life of a patent



From “Publish or Perish” to “Patent and Prosper”?



Novelty destroying: anything revealed about the invention in writing or orally before the patent application



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)



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**.

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.**

Who owns the patent?

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



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

I'm still confused...



... but on a much higher level!

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