

Intellectual Property Rights

IP Rights

Patent basics

Patentability

Patenting procedure

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Novelty vs. infringement in chemistry

Concluding remarks

**PD Dr. Peter Felder
European Patent Attorney
Schmauder & Partner AG
Zürich**

Intellectual Property and its protection

Intellectual Property (IP):

- Ideas
- Discoveries
- Inventions
- Creations, Acts
- Brands

Protection of IP Rights (IPR):

- Patents = Protection of technical inventions
- Industrial Designs = Protection of shapes (3D) and patterns (2D)
- Trademarks = Protection of brands
- Breeder's rights = Protection of plant varieties
- Copyright = Protection of acts (literature, arts, music) + software
- Law against unfair competition = a general protection tool

Trademarks

A trademark is an "identifier": it should make a link between a product or service and its source, i.e. the person/institution/enterprise behind it

It provides added value to the product or service by projecting an expectation of quality, goodwill, uniqueness etc.

The value of a trademark can be immense:

- google = USD 44 billion (2014)
-  = USD 4 billion (2015)

A trademark shall be distinctive and not descriptive:

- "apple" OK for computers, but not for a fruit juice

A trademark shall not be deceptive:

- "sana-star" OK for health food, but not for cigarettes

Some examples of trademarks

- Word mark

MIGROS

- Device mark

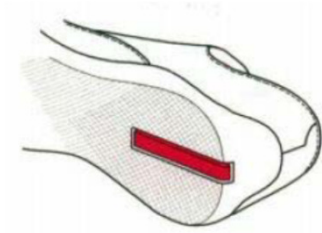


- 3D-mark



- Acoustic mark (= sound logo, «jingle»)

- Position mark



Note: trademark registrations can be renewed every 10 years

Firm's name

The firm's name identifies the company.

Very often, the firm name is also used as a brand for the company's products or services.

Important: registration of a company's name in the commercial register does not provide any registered trademark rights!

Use as firm (e.g. on letterhead):

Mepha Pharma AG

Use as trademark (e.g. on package):



A trademark registration is not a patent!

Swissregauszug - Marken

Auszug vom	:	01.12.2015
Marke Nr.	:	P-507946
Markeneintragungsgesuch	:	00566/2003
Hinterlegungsdatum / Beginn Schutzfrist	:	31.01.2003
Ablauf Schutzfrist	:	31.01.2023
Erste Veröffentlichung in	:	SHAB Nr. 52
Erste Veröffentlichung am	:	18.03.2003



SIMVASTIN-MEPHA

Inhaber/in

Mepha Schweiz AG
Kirschgartenstrasse 14
Postfach
4010 Basel

Waren und Dienstleistungen

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Pharmazeutische Erzeugnisse und Substanzen sowie Präparate für die Gesundheitspflege; medizinische Desinfektionsmittel.

Nizza Klassifikation Nr.

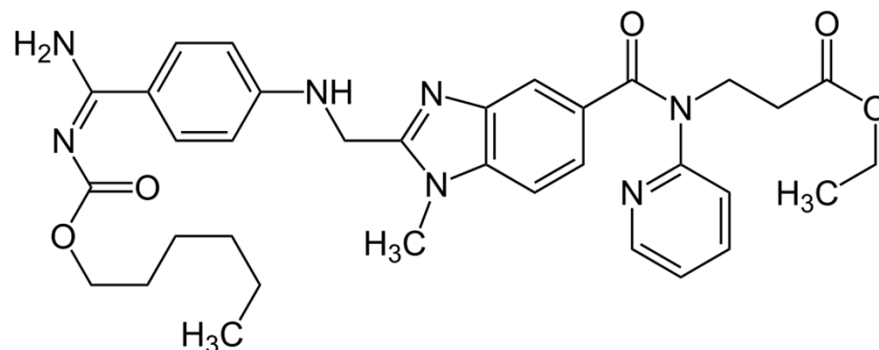
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Eintragung ins Markenregister

04.03.2003



Compound names, INN-names and trademarks of pharmaceutical substances



Ethyl 3-[[[2-[[[4-{N'-[(hexyloxy)-carbonyl] carbamimidoyl]-phenyl]-amino]-methyl]-1-methyl-1H-benzimidazol-5-yl]-carbonyl]-(2-pyridinyl)- amino]-propanoate

CAS-Number: 211915-06-9

INN-Name: Dabigatranetexilate (international nonproprietary name, WHO, free)

Trademark: Pradaxa[®] (selected by company, Boehringer Ingelheim, exclusive)

Other example: combination of INN and trademark: Amlodipin-Mepha[®]

Patents

A patent provides its proprietor with an exclusive right, i.e. a right of exclude others from making, using, selling, offering for sale, exporting or importing the patented invention.

A patent is directed against anyone; however, it is limited:

- substantively (according to the patent claims)
- temporally (according to the patent duration, usually up to 20 years)
- geographically (according to country selection)

Important:

A patent does not provide any positive rights:

- a patent for a pharmaceutical drug is not a permission to market the drug
- a patent does not exclude the infringement* of another party's patent

*infringement of a patent = violation of patent rights Patentverletzung

A patent is a sword, not a shield!

A patent is an intangible asset

Like the sale or rental of a substantive property (e.g. a house), a patent can be

- sold ("assignment")
- licensed

In doing so, the exclusivity rights provided by the patent are transferred either definitively to the new owner, or temporarily to the licensee, against payment of an agreed sale or license fee.

Determining the monetary value of a patent is very difficult!

The patent as a contract between society and inventor

"Rewarding principle":

- The inventor discloses its knowledge to the public (as described in the patent application)
- Society provides the inventor with a limited monopoly (as defined by the patent claims)

The patent specification is both a technical and a legal document!

Structure of patent documents

Description (= the technical part):

- Short summary of the relevant state of the art ("prior art")
- Problem to be solved by the invention
- Detailed technical description of the invention (US: "enabling disclosure")

Claims (= the legal part):

- Definition of the protection range
- Concise and clear (legal certainty for third parties!)
- Limited to one sentence (for historic reasons)

Protection scope

A patent claim is infringed if all the features of the claim are present in the competitor's product or method.

A patent claim is not infringed if an essential feature of the claim is missing in the allegedly infringing object.

A patent claim is like a check-list that describes the protected invention.

Claims with a large number of features have narrow protection scope!

Example

Short patent claim = broad protection:

- A furniture piece, comprising a plate element and a plurality of supporting elements attached at one side of the plate element.



Longer patent claim = narrower protection:

- A furniture piece, comprising a **rectangular** plate element **made of wood** and **four** supporting elements attached at one side of the plate element.



Types of patent claims and examples

Physical entities:

- Apparatus
 - cell cultivation device
 - heart rate monitor
- Product
 - blood-pressure lowering drug
 - monoclonal antibody with radioactive marker

Activities:

- Process
 - method for detecting oxygen concentration in blood
- Use
 - use of CRP level as marker for myocardial infarction

Typical chemistry claim

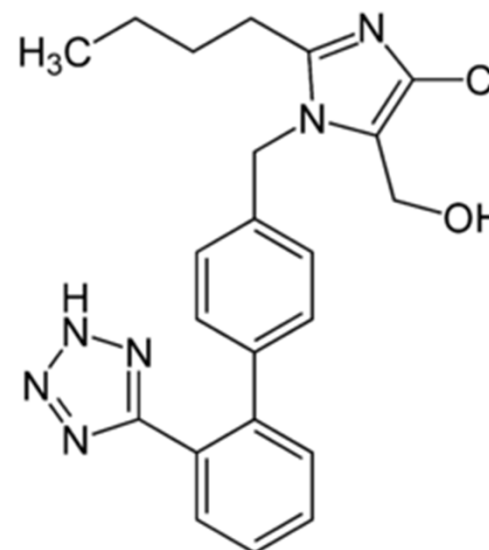
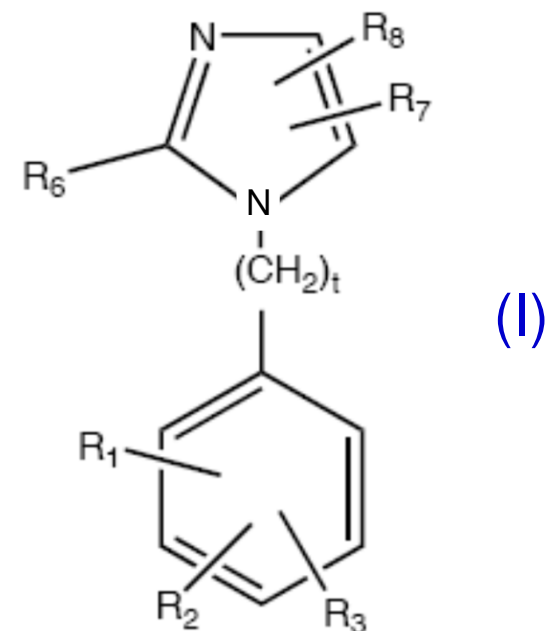
Example: EP 0 253 310 B1

A compound of formula (I), wherein

- $R_1 = \dots$
- $R_2 = \text{H, Cl, Br, } \dots, \text{ or Furyl,}$
- $R_3 = \text{H, Cl, Br, } \dots, \text{ or C}_{1-4}\text{-Alkoxy,}$
- $R_6 = \text{C}_{1-10}\text{-Alkyl, } \dots$
- $R_7 = \text{H, F, Cl, } \dots \text{ or CN,}$
- $R_8 = \text{H, CN, } \dots (\text{CH}_2)_n \text{OR}^{11}, \dots$
- $R_{11} = \text{H, } \dots$
- $t = 0 \text{ or } 1$

= thousands of compounds!

one of them is **Losartan**



Typical biotech claims

1. An emulsion containing a compound of general formula XXX and an anti-hypertrophic agent.
2. The emulsion of claim 1, wherein the compound is Z.
3. A composition for the treatment of disease ABC, comprising an emulsion containing a compound of general formula XXX and an anti-hypertrophic agent.
4. A kit of parts for the treatment of disease ABC, comprising a first medium containing XXX in aqueous solution and a second medium containing an antihypertrophic agent in an oily medium and means for mixing the two media.
5. A method of treating disease ABC, comprising the administration of the composition of claim 1 to a human patient.

Patentable inventions

Patents are granted for inventions that are new, involve an inventive step and are industrially applicable.

Not patentable as such:

- discoveries, theories, mathematical methods
- business methods
- computer software
- presentations of information

NB: in the US some of the above are patentable!

Strictly not patentable:

- methods for treatment of the human or animal body by surgery or therapy
- diagnostic methods practised on the human or animal body
- plant or animal varieties or essentially biological processes for the production of plants or animals;

however, this provision shall not apply to microbiological processes or the products thereof.

Patentable biotech inventions

Biotechnological inventions are patentable if they concern:

- biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature (e.g. novel and complicated extraction of an active agent from a plant)
- plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety,
- a microbiological or other technical process, or a product obtained by means of such a process.

Human body and its elements

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
- 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.
- The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Novelty

An invention shall be considered as new if it is not part of the state of the art.

The state of the art is considered to comprise everything that was made available to the public by means of a written or oral description, by use, or in any other way, before the filing date of the patent application.

Examples of novelty-destroying acts:

- prior publication (including own publications, "prepublications" in the Internet, unlike the USA!)
- presentation to an unrestricted circle of persons (beware of conference abstracts!)
- test sales

European practice (case law): Novelty vs. 1 prior art document

Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

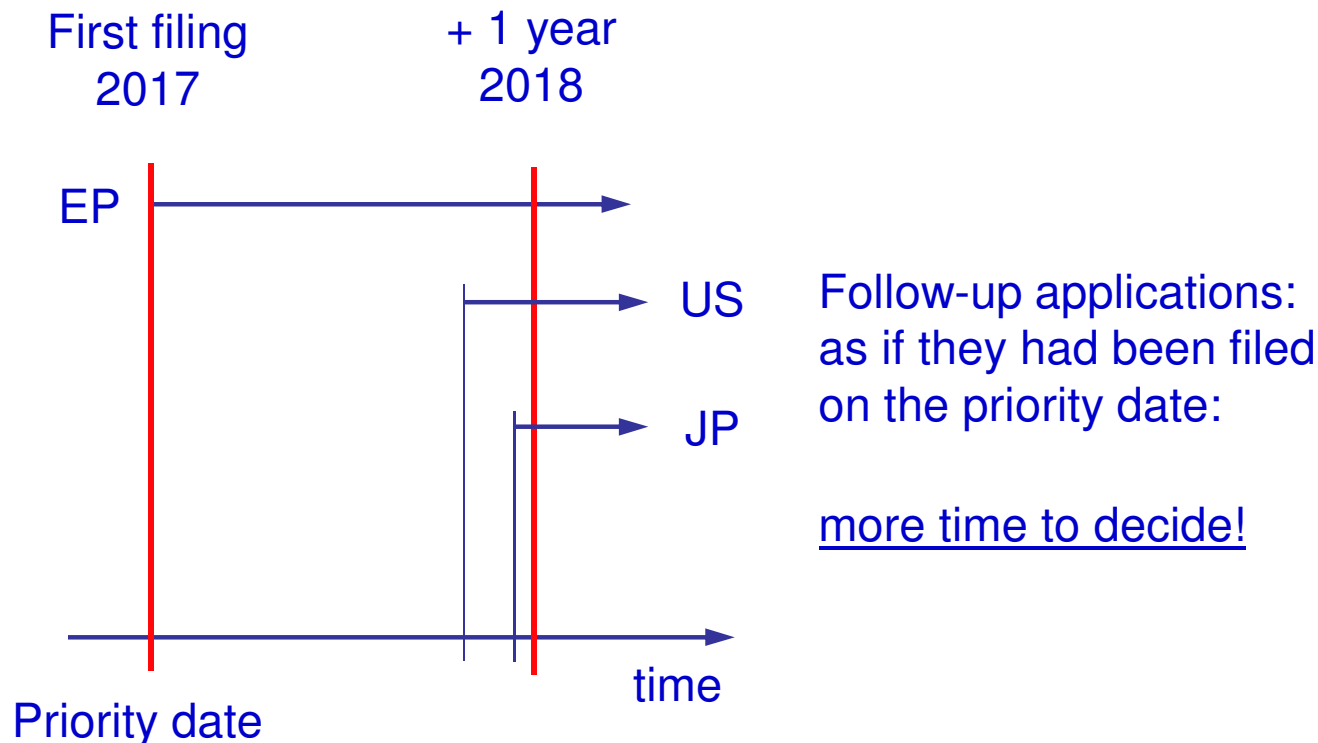
- No patent protection for trivial improvements!
- Positive Indicators: unexpected success, long-existing need, overcoming a prejudice in the technical field, critical parameter choice, synergistic effect ("more than additive").
- Negative indicators: straightforward designing, routine testing (low-dimensional parameter space), combination of known measures without synergistic effect.

European practice (case law): Inventiveness vs. 2 prior art documents

The patenting road

"Paris Convention": the first filing in any country establishes a so-called priority right, which is valid for 1 year.

Further applications for the same invention that are filed within one year are considered to have the same "seniority" as the first application.



Important moments in a patent's life

- Filing (deposit): defines filing or priority date
- Search: patent office determines the relevant prior art
- Application published: 18 months after the priority date the **public** is informed about a *potential* patent
- Examination: patent office determines patentability vs. prior art
- Decision to grant: patent office informs about allowable version
- Patent published: the **public** is informed about a *new* patent
- Opposition: competitors attack patent by claiming *invalidity*
- Enforcement: patent owner attacks competitor (cease & desist, damages)

Bundle patent applications

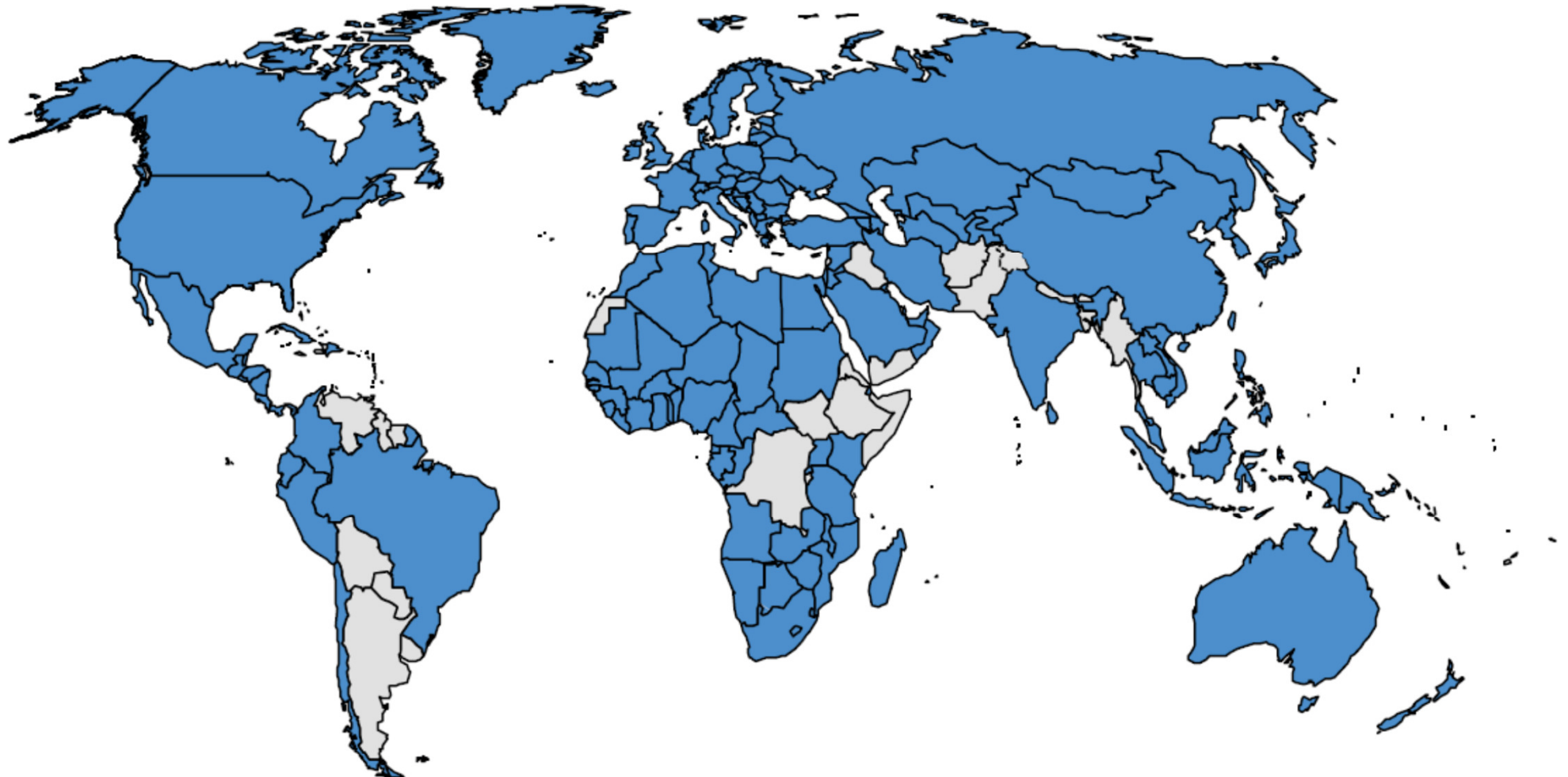
EPC (European Patent Convention, 38 States incl. CH):

- one filing, one examination procedure, leads to a unitary patent
- after grant: administered by the various EPC national offices

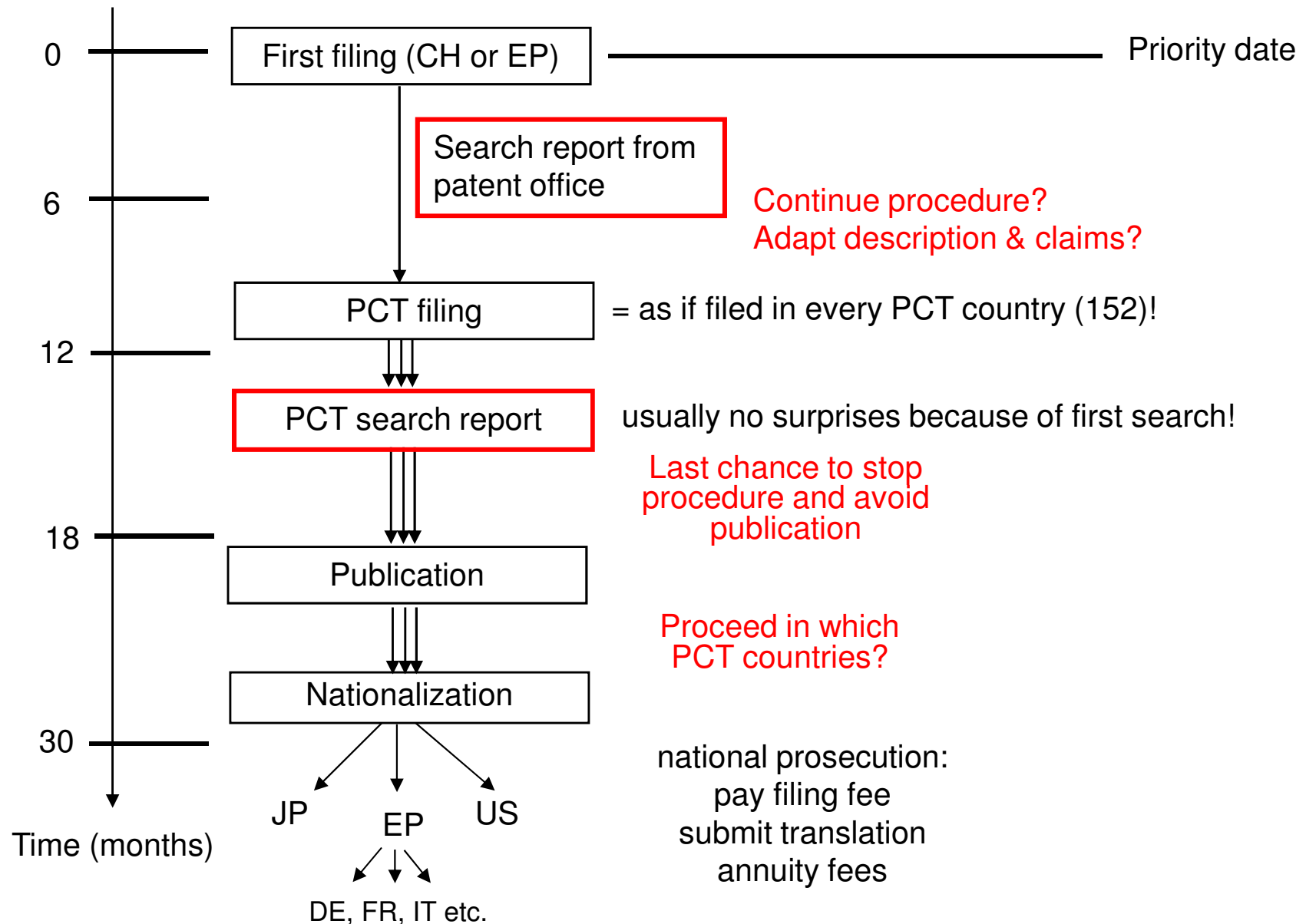
PCT (Patent Cooperation Treaty, 152 States incl. CH and EPC):

- one filing, = "worldwide" patenting option
- does not lead to a "world patent"
- 30 months after the priority date: "nationalization"
- examination in each one of the desired countries or regions
- leads to as many national or regional patent applications as desired

PCT: almost «worldwide»:



Typical international patenting procedure



Supplementary Protection Certificates (SPC)

Starting point:

- Protection term of a patent is 20 years from the filing date
- For medicinal and plant protection products one needs an official marketing authorization, which can take up to 10 years
- This cuts down on the effective lifetime of a patent

Compensation through SPC:

- SPC extends patent lifetime, but for the authorized product only!
- Starts on expiry of the basic patent and lasts for a duration corresponding to the time between patent filing and the first date of authorization, minus 5 years
- SPC duration is limited to 5 years

Pediatric extension of SPC (EU, to follow in CH):

- SPC lifetime increased for further 6 months in case of pediatric indication

Example Losartan Patents (Cosaar ®)

Patent No.	Expiry	Protection scope
EP 0 253 310	08. Jul 2007	Group of compounds Sartans, incl. Losartan
ESZ C00253310/01	20. Dez. 2009	Losartan
EP 0 533 840	06. Jun 2011	Indication: Sartan against chronic kidney failure caused by angiotensins
EP 0 733 366	04. Jan 2009	Combination: Sartan plus diuretic
ESZ C00733366/01	27. Feb 2012	Losartan plus Hydrochlorothiazide

Take home messages

- Patents are an important tool for keeping exclusivity of innovations
- Not every patent publication corresponds to a valid patent: the majority are published applications
- In general, patent protection lasts for 20 years at most. However, protection can be extended by up to 5 years for pharmaceuticals to compensate for delays in the regulatory approval process
- Patents can be a door-opener: cross-licensing
- Patentability requires absolute novelty and an inventive step
→ **patent now, publish and sell later!**
- The infringement of a competitor's patent can have serious consequences → check the patent situation before launching a new product!
- Having a patent does not protect against other's patents!

Interesting Links

General information:

- www.ige.ch Swiss Federal Institute of Intellectual Property
- www.epo.org European Patent Office
- ww.wipo.int World Intellectual Property Organization
- www.uspto.gov US Patent and Trademark Office

Free databases:

- <http://ep.espacenet.com/>
 - worldwide search for patent documents (pending applications and granted patents)
 - download of patent documents (PDF)
 - only limited information about current status!
- www.swissreg.ch
 - search for Swiss IP rights (patents, trademarks, etc.) including full status

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