PATENTTI- JA REKISTERIHALLITUS
Tule ja onnistu.

PATENTS IN LIFE SCIENCE BUSINESS

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Head of Division for Chemical Technology
Patents and Trademarks
Finnish Patent and Registration Office (PRH)

Agenda

1. Why IPRs do matter?
2. Different ways of utilizing patent system
3. What can be patented? - Criteria and exclusions
4. Patenting of pharmaceuticals
5. Patenting at home and abroad
6. Patents, business, life

Finnish Patent and Registration Office (PRH)

WE REGISTER

- companies
- housing companies
- foundations
- associations
- enterprise mortgages

WE EXAMINE AND GRANT

- patents & utility models
- trademarks
- registered designs

WE SUPERVISE

- foundations
- auditors

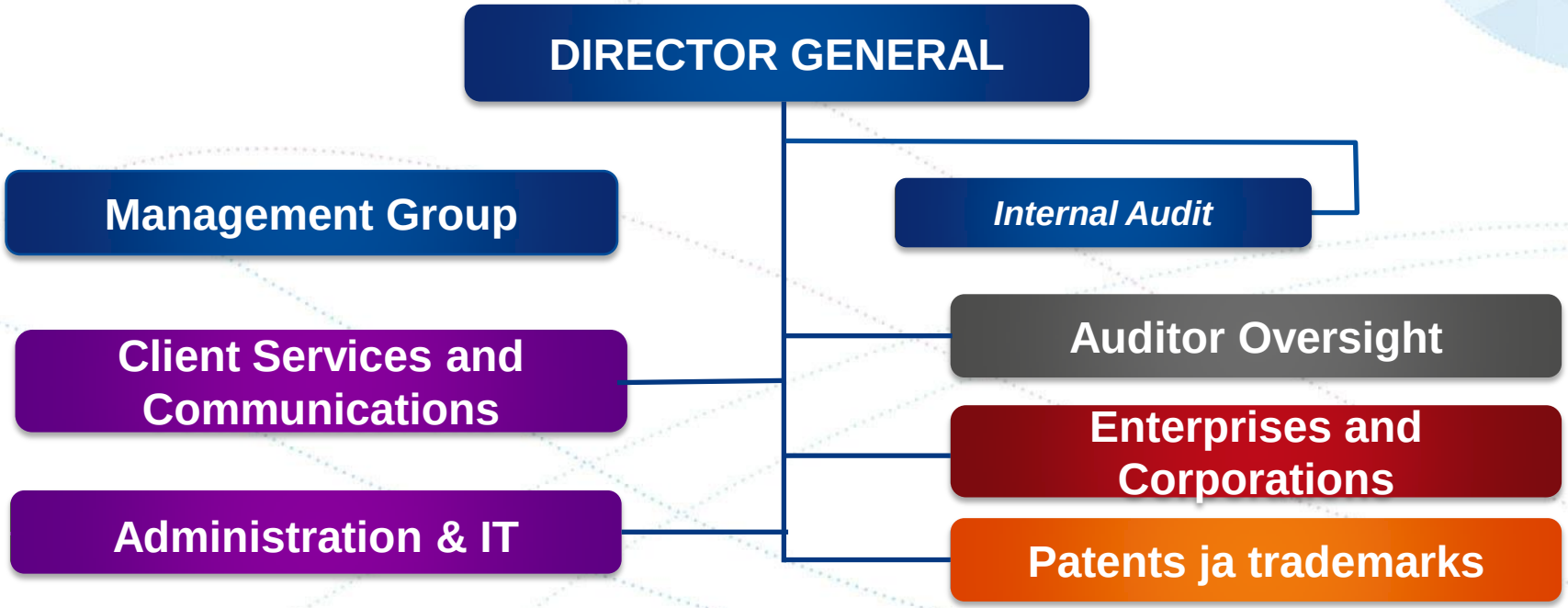
WE TRAIN AND GIVE ADVICE

- customer support
- information and
- training services

The customer is number 1

PRH PATE PRH FINNISH PATENT AND REGISTRATION OFFICE

Organisation



Co-operation networks & local services

Enterprise agencies | Team Finland | Enterprise Finland

Staff and finances 2015

STAFF

Number of personnel:

c. 400 persons

Work satisfaction:

3,75 (scale 1-5)

INCOME AND EXPENDITURE

Income

49,5 million euro

Expenditure

52,4 million euro

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Customer volumes 2015

160,000
trade register
notifications

110,000
answered
customer calls

1,400
national
patent applications

Over
4,000
Twitter
followers

3,300
national
trademark
applications

28,000
face-to-face
customers

PRH PATEI PRH FINNISH PATENT AND REGISTRATION OFFICE

We help companies throughout their life-cycle

- Limited liability companies and co-operatives come into existence when registered at the Trade Register
- Business ID – one single ID for each business operator

Intellectual Property Rights:

- Patents and Utility Models
- Trademarks
- Registered Designs
- Company Names

Business Information:

- Business Information System (with the Tax Administration)
- Patent and Trademark databases
- Open data

PRH PATEI PRH FINNISH PATENT AND REGISTRATION OFFICE

PRH EXAMINES AND GRANTS INDUSTRIAL PROPERTY RIGHTS

BRANDING OF COMPANIES & PRODUCTS

- Company names
- Trademarks
- Registered designs

INVENTIONS & INNOVATIONS

- Patents
- Utility models

Other immaterial rights: Copyright and domains

COPYRIGHT

- Ministry of Culture and Education

DOMAINS: .FI

- Finnish Communications Regulatory Authority

PRH PATENTTI- JA REKISTERIHALLITUS FINNISH PATENT AND REGISTRATION OFFICE

Our multi-channel services

ONLINE SERVICES

- Filing for patents, trademarks and designs
- Notifications to the Trade Register and Register of Associations

INFORMATION SERVICES

- Data on companies, associations, foundations and auditors
- Data on patents, trademarks and registered designs

SEARCH AND EXAMINATION SERVICES

- Freedom to operate report
- Patentability report
- Novelty search
- Online preliminary examination of the invention
- Preliminary examination of trademarks

ADVICE AND TRAINING SERVICES

- Basic and advanced advice/customer support via
  - Chat
  - Phone
  - Email
  - Face-to-face
- Training courses and seminars
- websites: prh.fi ja ytj.fi

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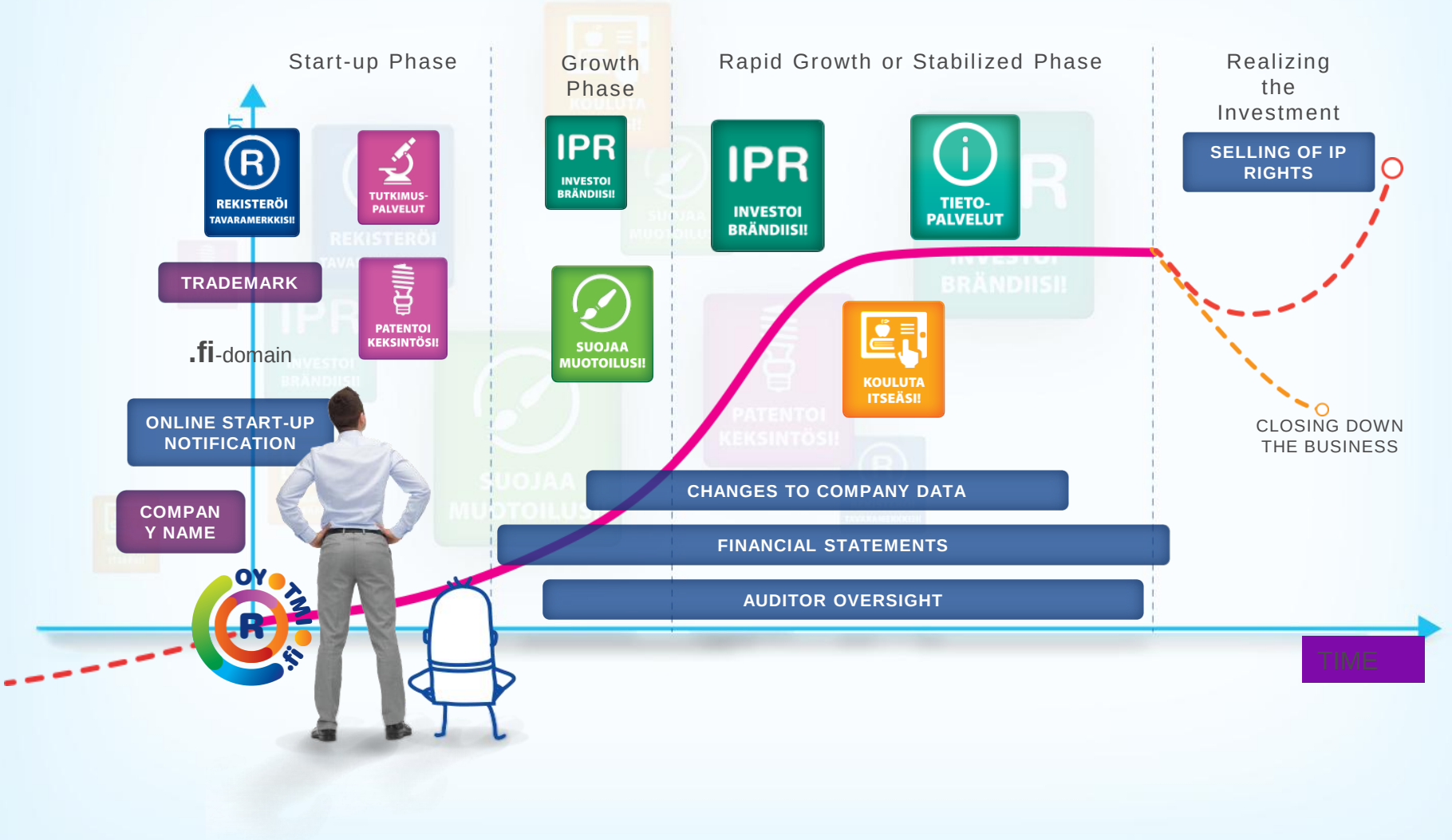
PRH Services and Company life-cycle



Why IPRs do matter?

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One product – several ways to protect

Patents and utility models
- Technical components
- Computing methods
- Operating Systems
- User Interfaces
- Applications

Trademarks
- Company name
- Product name
- Logo
- Tone symbol

Design models
- Product design
- Display position and layout

Copyright
- Computer programs
- User guides
- Music
- Pictures

Business secrets
- Technical solutions and knowledge that can be kept secret

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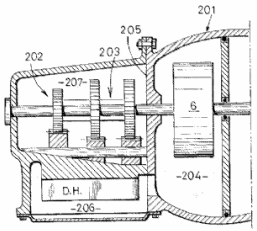
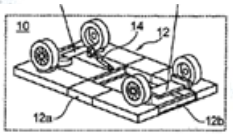
Intellectual Property Rights in PRH





Google

Nokia Oyj

Right	What is protected?	How?
Patent	New invention	Patent application and examination
Utility model	New invention	Utility model application and registration
Trademark	Specific name/label of product or service	Trademark application and registration
Design model	New product appearance	Design model application and registration
Business name	Name of company	Name registration to trade register

PRH FINNISH PATENT AND REGISTRATION OFFICE

Why IPRs do matter

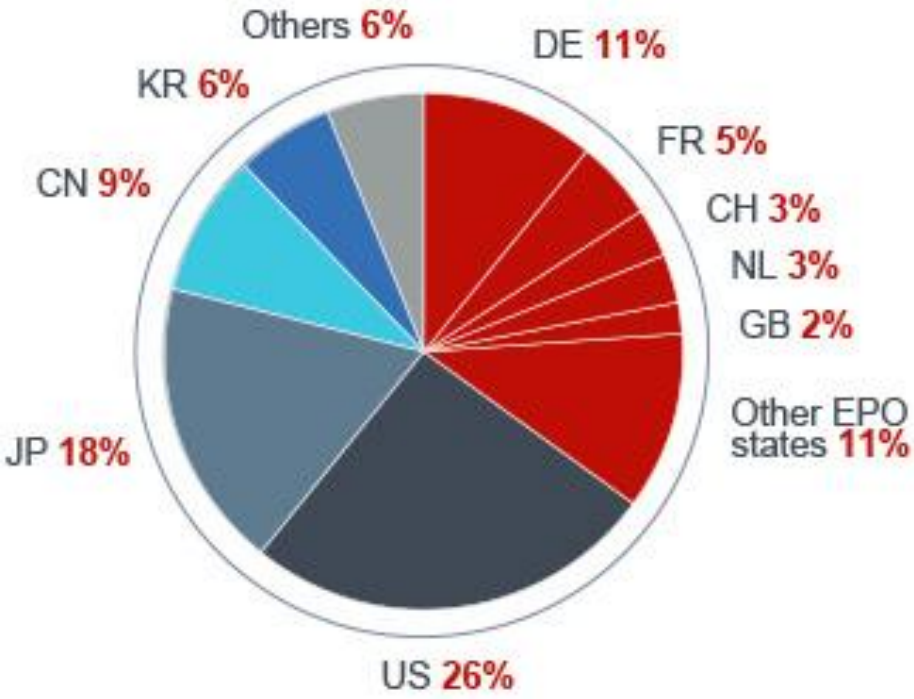
- In the EU, intellectual property rights (IPR) intensive industries generate 39 % of gross domestic product (GDP) and 35 % of all jobs
- Companies owning IPRs have, in general, 29% higher revenue per employee, about six times as many employees and pay wages that are up to 20% higher than firms which do not own IPRs
- For start-ups, a patent portfolio predicts likelihood to success

Sources:

- Alkaersig et al. Intellectual Property Rights Management, Palgrave Macmillan, UK, 2015, 190 p
- Méniere et al., Patent positions and start-up success, IAM, 2015
- Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union, EPO & OHIM, 2013
- Intellectual property rights and firm performance in Europe: an economic analysis, EPO & OHIM, 2015

Statistics: Europe Patent Office (EPO)

- Patent filings at the EPO grew by 3.1 % in 2014, hitting a new record high of over 274 000
- But highest growth by
  - China (+18 %)
  - US (+7 %)
  - KR (+2 %)
- Europe: +1.1 %
- Germany: +/- 0 % (31 647)
- Sweden: +/- 0 % (5132)
- Finland: - 9 % (2472)

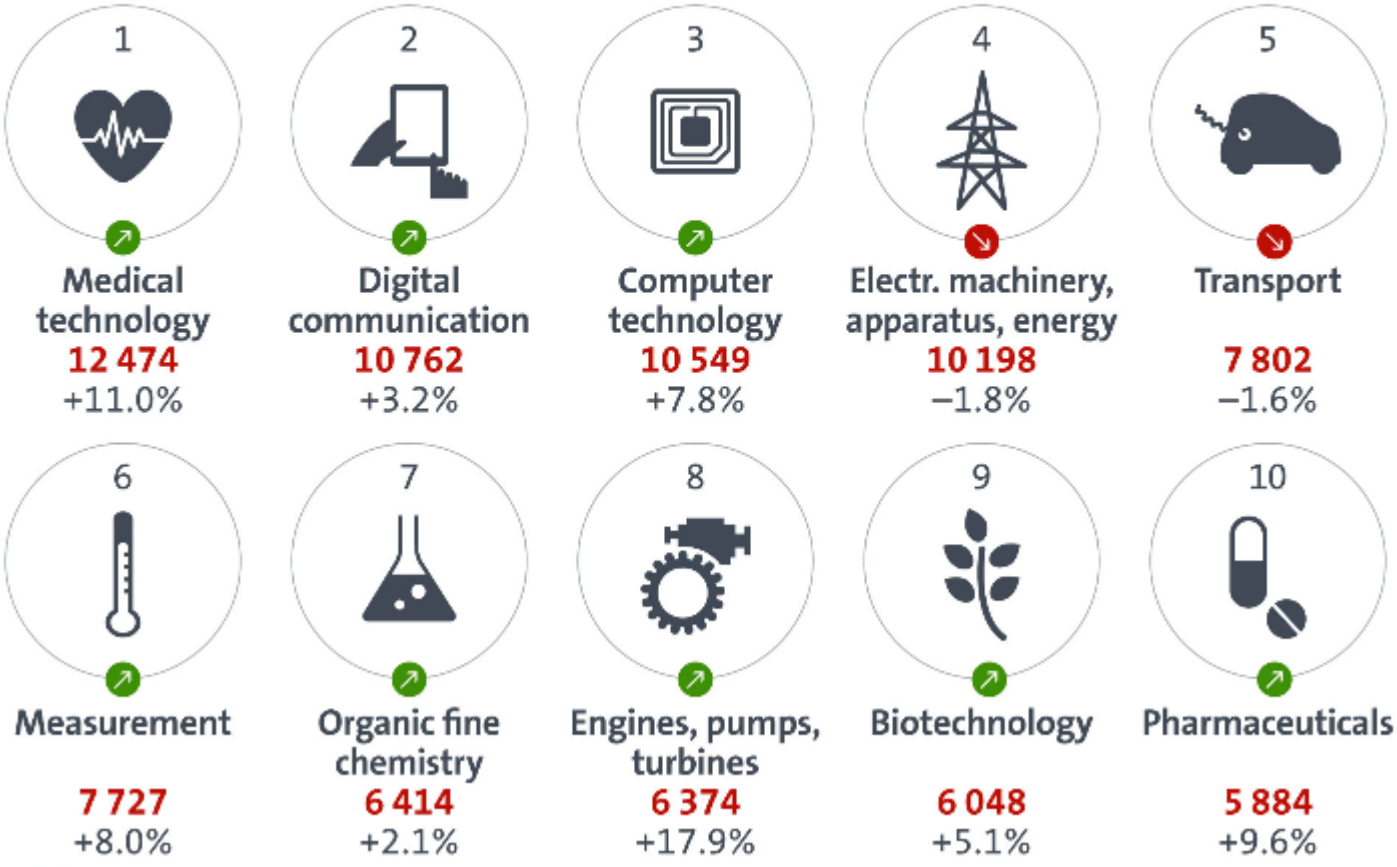


Source: EPO (2014)

FINNISH PATENT AND REGISTRATION OFFICE

Anmeldestärkste technische Gebiete
Technical fields with most applications 2015
Les secteurs technologiques les plus actifs

TOP 10



EPO 2016

Source: EPO

FINNISH PATENT AND REGISTRATION OFFICE

Different ways of utilizing patent system

Protecting own IPR

Creating business assets

Information to R&D

FINNISH PATENT AND REGISTRATION OFFICE

What is a patent?

- A patent is an **exclusive right**, which means that only you can exploit your invention.
  - This refers to commercial exploitation, such as making, selling, using and importing the invention.
  - You can sell your patent or license someone to commercially utilise the patented invention.
- A patent is in force in the countries where it has been applied for and granted (**territorial right**)
- The patent is in force for **a limited period of time**, usually no longer than for 20 years from the filing date of the application.
- To keep a patent in force, you have to pay annual fees.
- After 18 months patent becomes **public** (unless withdrawn)
  - Precise technical description advances the state of the art

PRH PATENTTI- JA REKISTERIHALLITUS

Patenting: Creating business assets

- Strong market position – Prevents others from using your invention; higher return of investments
- Marketing – A positive image of you and “an Innovative label” on your product
- Value of your business – Patents have value as such
- Attracts investors – Patent portfolio demonstrates expertise and technological capacity within the company
- Source of income – License out or sell the invention
- Negotiation power – Cross licensing (exchanging patent rights) with another company

Use patent information for planning business strategy

- Identify business partners, suppliers and materials
- Licensing in/out, cross-licensing, selling/buying inventions
- Monitor activities of your competitors
- Plan investments, commercial and R&D activities
- Identify niche markets
- Avoid possible infringement problems
- Do you have freedom-to-operate?

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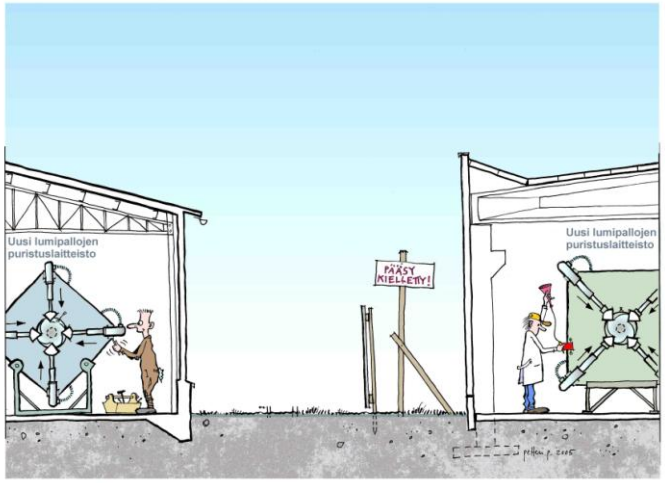
Use patent information for planning R&D strategy

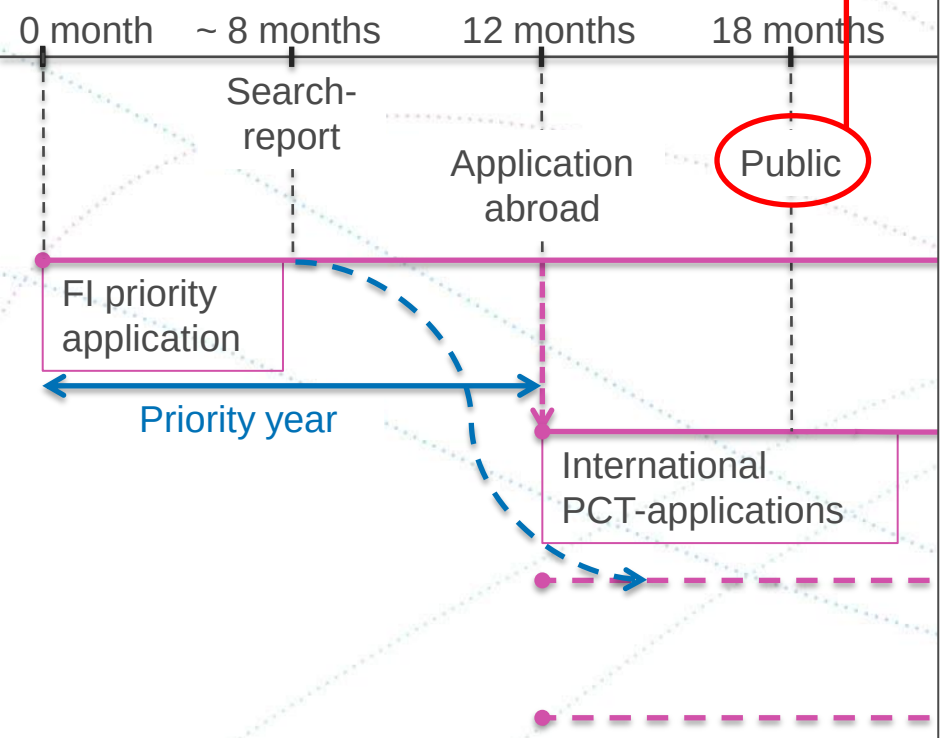
- Learning about current trends in research and innovations
- Avoid unnecessary costs and find out already known solutions to technical problems
  - Do not invent the wheel again
  - Overlapping R&D work level 30..50%
  - IP information often (70..90%) available only through IP (over 30 million), not over conference papers
- Identify alternative technologies
  - Competing technologies, alternative solutions
- Get ideas for further innovation

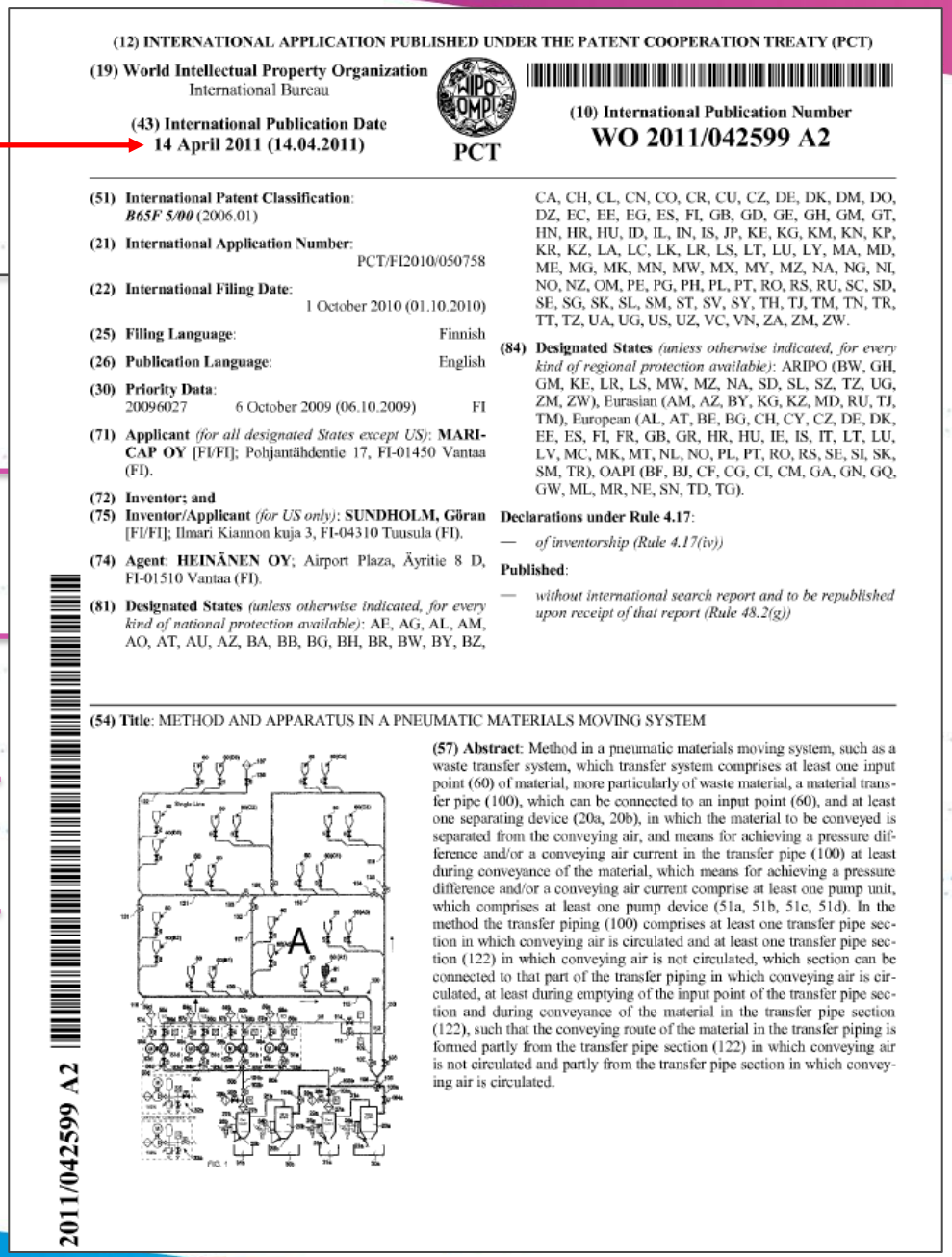


Don’t let the patent terminology drive you away:

- Don’t start from the beginning
- Check what the inventors have actually done: see the examples!
- Check the figures!
- Use patent classification symbols in the searches: helps you find most relevant documents

Patent documents





(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 April 2011 (14.04.2011)

PCT

(10) International Publication Number
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(51) International Patent Classification:
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(22) International Filing Date:
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(25) Filing Language: Finnish

(26) Publication Language: English

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20096027 6 October 2009 (06.10.2009) FI

(71) Applicant *(for all designated States except US)*: **MARICAP OY** [FI/FI]; Pohjantähdentie 17, FI-01450 Vantaa (FI).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **SUNDHOLM, Göran** [FI/FI]; Ilmari Kiannon kuja 3, FI-04310 Tuusula (FI).

(74) Agent: **HEINÄNEN OY**; Airport Plaza, Äyritie 8 D, FI-01510 Vantaa (FI).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) Title: METHOD AND APPARATUS IN A PNEUMATIC MATERIALS MOVING SYSTEM

(57) **Abstract**: Method in a pneumatic materials moving system, such as a waste transfer system, which transfer system comprises at least one input point (60) of material, more particularly of waste material, a material transfer pipe (100), which can be connected to an input point (60), and at least one separating device (20a, 20b), in which the material to be conveyed is separated from the conveying air, and means for achieving a pressure difference and/or a conveying air current in the transfer pipe (100) at least during conveyance of the material, which means for achieving a pressure difference and/or a conveying air current comprise at least one pump unit, which comprises at least one pump device (51a, 51b, 51c, 51d). In the method the transfer piping (100) comprises at least one transfer pipe section in which conveying air is circulated and at least one transfer pipe section (122) in which conveying air is not circulated, which section can be connected to that part of the transfer piping in which conveying air is circulated, at least during emptying of the input point of the transfer pipe section and during conveyance of the material in the transfer pipe section (122), such that the conveying route of the material in the transfer piping is formed partly from the transfer pipe section (122) in which conveying air is not circulated and partly from the transfer pipe section in which conveying air is circulated.

WO 2011/042599 A2

Searching patent documents

E.g. espacenet (free of charge)

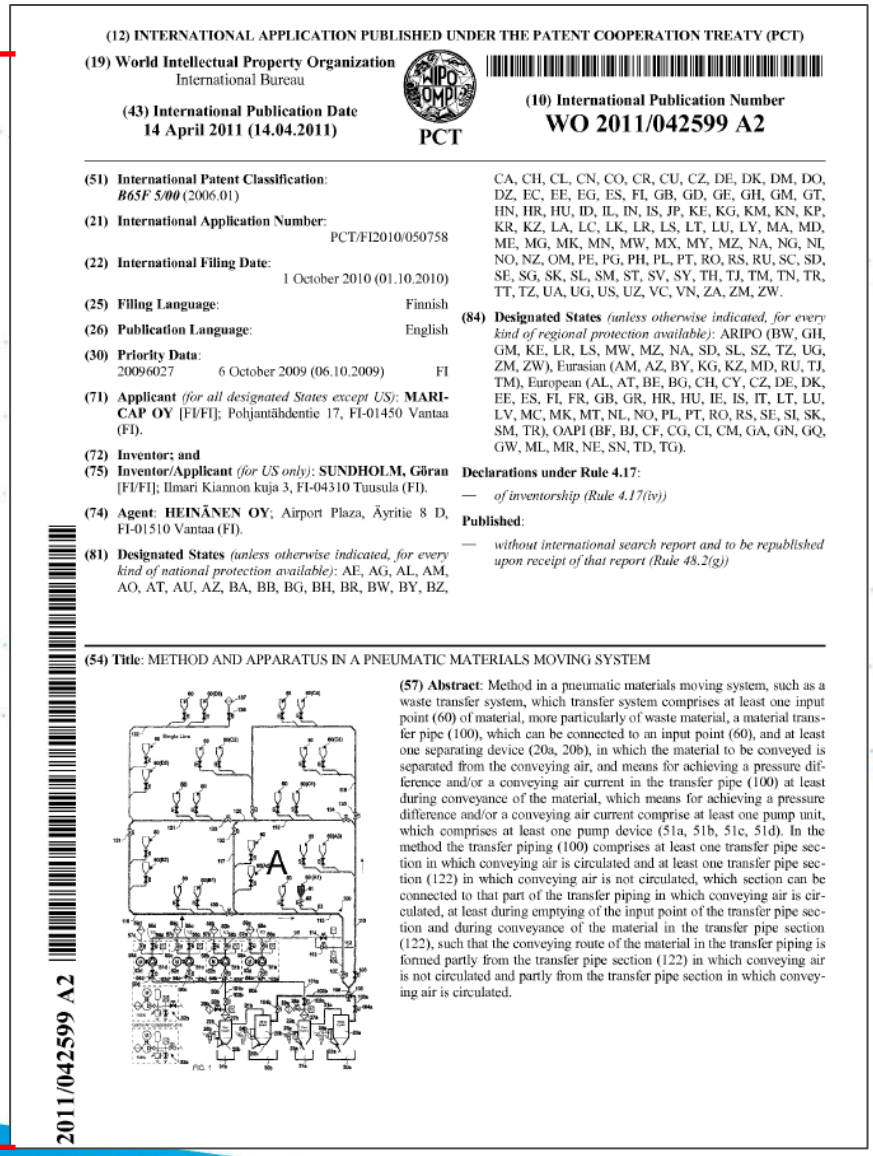
- Bibliographic information (inventor, applicant)
- Title, abstract (and fulltext)
- Patent classification
  - Inventions are classified by patent offices using same classification systems (IPC, CPC)
  - Inventions consisting of same features have same classification
  - Hierarchy!
  - B65F5/005

    B65 = CONVEYING; PACKING; STORING; HANDLING THIN OR FILAMENTARY MATERIAL

    B65F = GATHERING OR REMOVAL OF DOMESTIC OR LIKE REFUSE

    B65F5 = Gathering or removal of refuse otherwise than by receptacles or vehicles

    B65F5/005 = by pneumatic means, e.g. by suction



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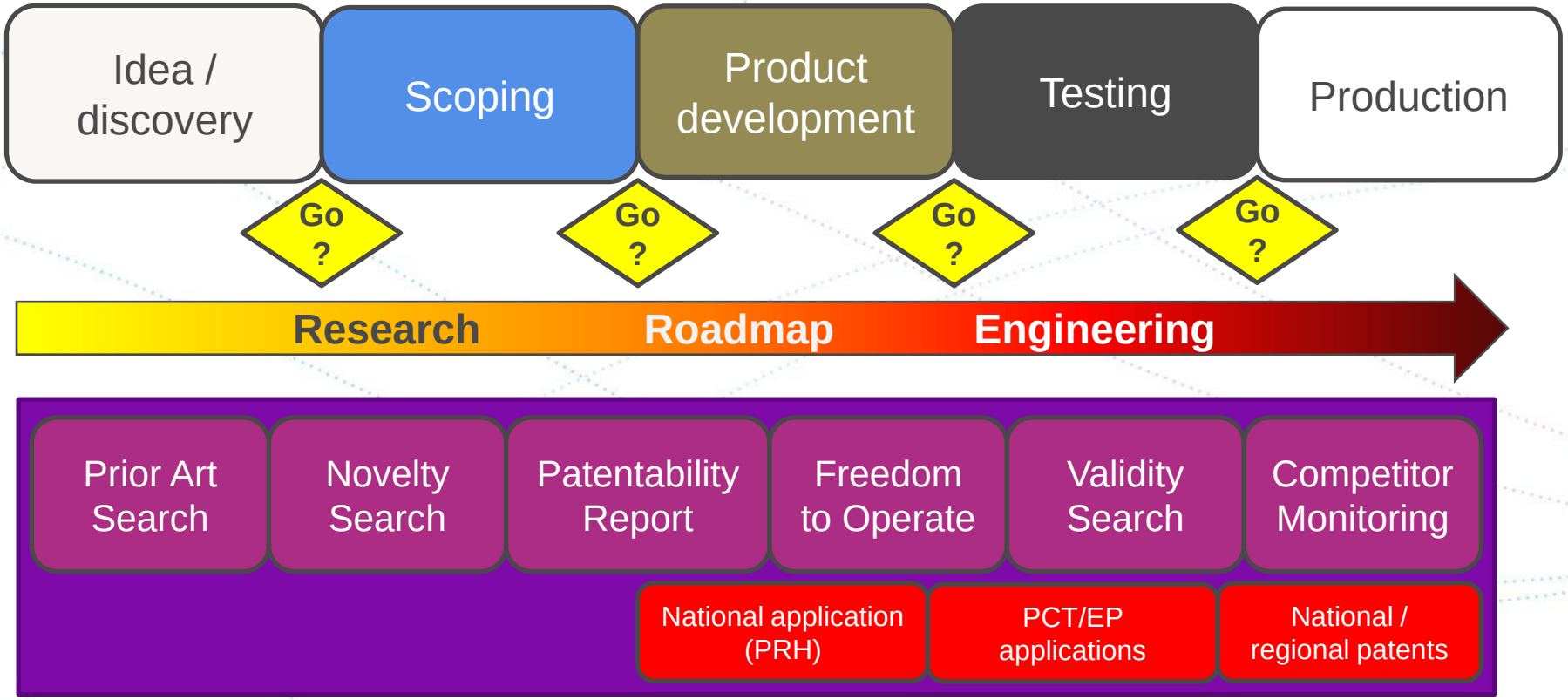
WO 2011/042599 A2

Stage-Gate considerations



FINNISH PATENT AND REGISTRATION OFFICE

Services at PRH

Alternatives to patenting

- Keep the invention secret
  - Can be applied only if the invention is difficult or impossible to be revealed by the final product
  - Contains risks:
    1) someone else later makes the same invention and obtains a patent for it
    2) someone else finds out the inventive idea from your product and starts manufacturing the same product
- Publish the invention
  - No one can patent the invention anymore
  - The invention is free to be used by anyone even industrially
- Combination (secret, patent, publish)

What can be patented? - Criteria and exclusions

A Finnish / European perspective

FINNISH PATENT AND REGISTRATION OFFICE

Criteria to patentability

PRH PATENTTI- JA REKISTERIHALLITUS

Patent system in Finland

- Based on Finnish legislation:
  - Patents Act
  - Patents Decree
  - Patent Regulations
- National Patent Laws are typically quite similar to each other due to international harmonization
  - Paris Convention
  - European Patent Convention (EPC)
  - TRIPS agreement
  - Patent Co-operation Treaty (PCT)
  - Etc.

Patent application

Application can be done in Finnish, Swedish or English – collegial procedure according to filing language

- **Description** of your invention
  - so clear that a person skilled in the field is able to use the invention
  - at least one detailed example of how the invention can be applied. In some cases, you must give more than one examples, as the example must illustrate all claims
- **Claims**
  - the claims set out what is protected by the patent
  - patent examiners assess the patentability of your invention by examining the claims and comparing the invention defined in them to solutions that already exist
- **Drawings**
  - To illustrate the invention,
  - the figure only shows the most important details of the invention using reference numbers or letters.
- **Sequence listing**
- **Abstract**
- Prepare your patent application carefully right from the start, as you have very limited possibilities to add or change any details in the application later.

Patentable subjects under Finnish law

- Three main criteria: Novelty, Inventive step, Industrial applicability
- Industrial applicability is interpreted broadly
  - For example, agriculture is interpreted as an industry
  - Any physical activity comprising technical features
- Can be, for example:
  - A product
  - A use of a product
  - A process (method)
  - An apparatus
- The invention must be possible to implement by a person skilled in the art => repeatable (sufficiency of disclosure)

Novelty

- Patent claim is divided into technical features
  - For example, “an apparatus comprising feature F1 and feature F2 characterized in that it comprises also features F3-F5”.
- Novelty search is conducted to establish the state of the art at the time of the application (or priority date)
  - State of the art includes **all public material** (patents, academic publications, Internet articles, journals, conference presentations etc.)
  - Public material must have a reliable publication date
- Claim is not novel if all features are disclosed in a single publication (published before the application/priority date)

Remember to file the patent application before you publish scientific paper, thesis, …! Most countries DO NOT have a grace period

Inventive Step

- If the claimed subject matter is not novel, it is not inventive either
- If the subject matter is not obvious to person skilled in the art, it contains an inventive step
  - The person skilled in the art has in disposal the most relevant technical material that is public at the time of the application
- Examination process usually establishes good understanding on “standard design choices for a person skilled in the art”
- “A person skilled in the art” knows state of the art at the application (priority) date
  - Can access all public documents
  - Can combine knowledge disclosed in a public document to general knowledge in the art

Industrial Applicability

- Usually the subject matter of claims is industrially applicable if it: **Can be made or used in industry**
- Industrial applicability necessary for a patent, but alone it is not good indication about patentability
  - if the subject matter of the claims is neither novel nor inventive, but is industrially applicable, likelihood to gain a patent is not high
- Some reoccurring examples of industrially non-patentable subjects
  - Perpetual movement machines, often novel and often not obvious to person skilled in art, but contrasts with basic laws of physics
  - Technical **effect** not well defined
  - Desired effects instead of technical features
    - *e.g., "apparatus … that makes communication more efficient" sounds more like a wish than a solution*

Sufficiency of disclosure

- Description must disclose any feature essential for carrying out the invention in sufficient detail to render it apparent to the skilled person how to put the invention into practice.
- Sufficiency in case of “biological material”?
  - "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.
  - Is the biological material available to the public?
    - YES: The biological material may be known to be readily available to those skilled in the art (e.g. baker's yeast) which is commercially available, it may be a standard preserved strain, or other material which is known to be available to the public without restriction
    - NO: The biological material is not available to the public and if it cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art
  - If YES, characteristics of the biological material have to be disclosed
  - If NO, then for the reasons of clarity and sufficiency of disclosure a sample of the biological material shall be deposited with a recognized depositary institution
    - the application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material;
    - the depositary institution and the accession number of the deposited biological material are stated in the application,

Some examples

- A bacterial mixed population, c h a r a c t e r i z e d by comprising Bacillus sp. DT-1 having the deposit number DSM 12560, Pseudomonas azelaica DT-2 having the deposit number DSM 12561, and Rhizobium sp. DT-5 having the deposit number DSM 12562
- Method of purifying waste water, c h a r a c t e r i z e d in that the water is biologically purified by microorganisms belonging to the group *Bacillus* sp. DT-1 having the deposit number DSM 12560, *Pseudomonas azelaica* DT-2 having the deposit number DSM 12561, and *Rhizobium* sp. DT-5 having the deposit number DSM 12562
- Use of bacterial strain *Lactobacillus* sp. 96/142 (DSM 15298) in the production of exo- polysaccharides applicable to improving of food structure.

Budapest treaty

- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
- Recognized International Depository Authorities
  - Requirements set out in the Treaty
  - In Finland, VTT Culture Collection was recognized in 2010
  - www.wipo.int/treaties/en/registration/budapest/guide/index.html

Exclusions to patentability

PRH PATENTTI- JA REKISTERIHALLITUS

Exclusions to Patentability

- Sections 1, 1a and 1b of Patents act list subject matter that is not regarded as an invention and cannot be patented
  - many of these exceptions relate to **biotech or medicine**

Exclusions to patentability section 1 of Patents act

- The following, as such, shall not be regarded as inventions:
  - discoveries, scientific theories and mathematical methods
  - aesthetic creations
  - schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
  - presentations of information
- As such, these are abstract ideas/mental acts that do not have a technical effect or industrial use

Exclusions to patentability:
surgical or therapeutic methods (section 1 of Patents Act)

- surgical and therapeutic methods practiced on humans or animals are not regarded as inventions
  - doctors must be free to practice their profession
- A multi-step method that comprises at least one surgical/ therapeutic step is considered surgical/therapeutic
- “therapy”
  - curing of a disease or malfunction of the body
  - prophylactic treatment (vaccination, immunostimulation etc.)
- “surgery”
  - the nature of the treatment is decisive, not its purpose (therapeutic/non-therapeutic surgery)

Exclusions to patentability: diagnostic methods (section 1 of Patents Act)

- Diagnostic methods practiced on humans or animals are not regarded as inventions
  - doctors must be free to practice their profession
- "diagnostic method"
  - method providing results that make it directly possible to decide on a course of medical treatment
  - methods for merely obtaining information from the human or animal body are not excluded
    - *X-ray investigations, MRI studies, blood pressure measurements*
- "practiced on humans or animals"
  - all technical method steps must be carried out in the presence of a human or an animal
  - exclusion does not apply to *in vitro* methods

In vitro methods are not excluded

EP2013365 B1

USE OF THE ORNITHINE TRANSCARBAMYLASE (OTC), AS A MARKER FOR DIAGNOSING BRAIN DAMAGES

Claim 1: A method for *in vitro* diagnosing mild cognitive impairment, Alzheimer's disease or non-Alzheimer's disease dementia in an individual, comprising a step of detecting ornithine transcarbamylase (OTC) in a sample of cerebrospinal fluid from said individual, wherein the presence of OTC in the cerebrospinal fluid is indicative of a brain disease.

EP 2437067 B1

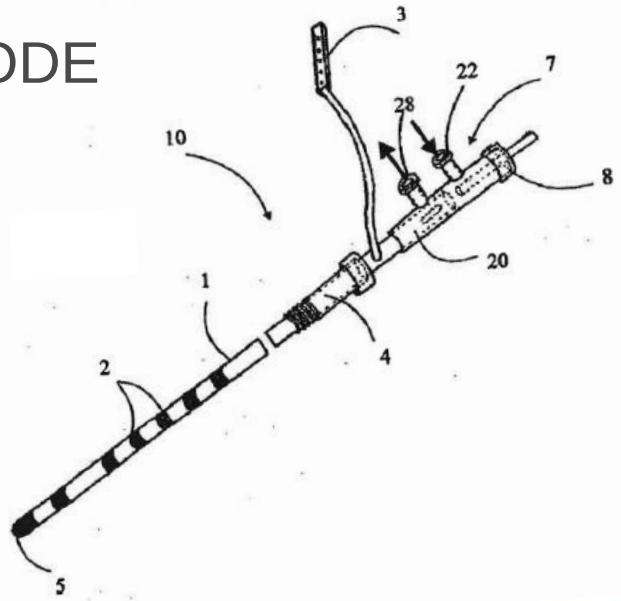
METHOD OF DIFFERENTIALLY DIAGNOSING DEMENTIAS

Claim 1: An *ex vivo* method of differentially diagnosing frontotemporal lobe degenerations, comprising a step of determining in a body fluid obtained from a patient the ratio of the absolute concentration of Aβ1-38 to the concentration of total amyloid β (Aβ1-38 %)

Products used in therapeutic, surgical or diagnostic methods are not excluded

- devices, substances, compositions, instruments, prostheses…

EP 2528501 B1 INTRACEREBRAL ELECTRODE
Claim 1: Intracerebral electrode (10, 11) including a narrow, elongated body (1) that is intended to be implanted in the brain of a patient…



EP 2611457 B1 COMPOSITIONS AND METHODS FOR TREATING FRIEDREICH'S ATAXIA WITH INTERFERON GAMMA

Claim 1: Interferon gamma for use in the treatment of Friedreich's Ataxia

Methods that are not diagnostic, surgical or therapeutic are not excluded

EP 2416698 B1 METHOD AND SYSTEM FOR TRAINING OF PERCEPTUAL SKILLS USING NEUROFEEDBACK

Claim 1: Method for training of a perceptual skill, comprising
- measuring electrophysiological activity in reaction to a sequence of perceptual stimuli
- matching the measured electrophysiological activity signal with a predefined electrophysiological signature signal, in which the predefined electrophysiological signature signal corresponds to an early electrophysiological component, and
- providing feedback when a match is detected,
wherein
- the sequence of perceptual stimuli comprises a number of stimuli of a first category and a stimulus of a second type occasionally appearing in the sequence of stimuli, and **characterized in that** it
- further comprises generating a new sequence of perceptual stimuli, in which the difference between stimuli of the first type and the stimulus of the second type is dependent on the strength of the measured electrophysiological signal.

Exclusions to patentability:

plant/animal varieties

essentially biological processes for the production of plant or animals

- Patents shall not be granted for plant or animal varieties or for essentially biological processes for the production of plants or animals (section 1 of Patents act)
- “essentially biological”
  - a process containing steps in which crossing and selection is carried out; selective breeding methods
- No exclusion of plants or animals if the invention can be carried out in more than one plant or animal variety
- No exclusion of methods of producing plants or animals that do not involve crossing and selection steps
- Transgenic/knock-out plants are animals as well methods of producing them are (usually) not excluded

EP 0971033 B1 TEST AND MODEL FOR ALZHEIMER'S DISEASE

Claim 1: A transgenic mouse comprising a recombinant polynucleotide including a nucleic acid sequence encoding a mutant human amyloid precursor protein (APP) allele that cosegregates with a genetic predisposition to Alzheimer's disease.

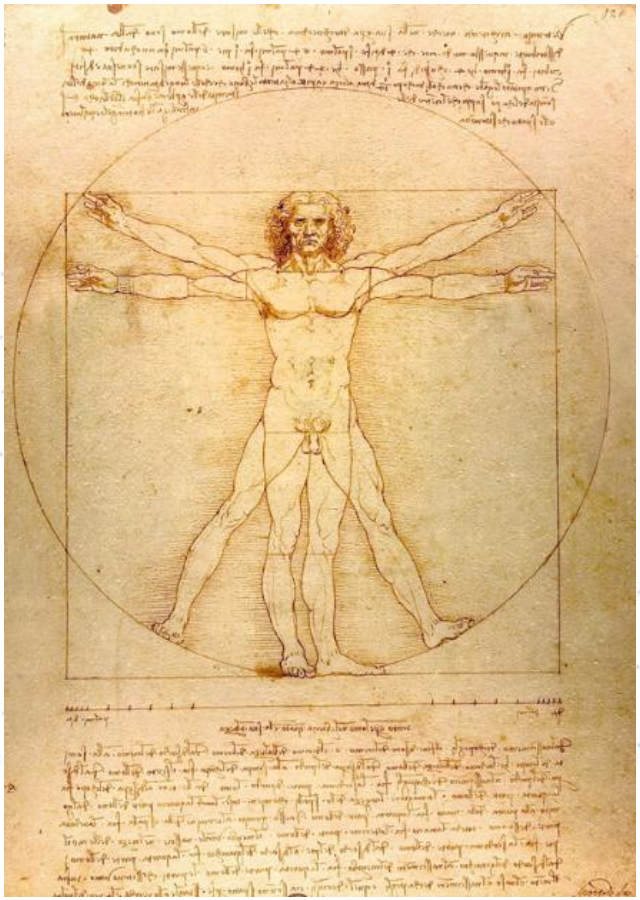
EP 2246434 B1

A GNMT- KNOCKOUT MOUSE MODEL FOR DEPRESSION, SCHIZOPHRENIA AND ALZHEIMER'S DISEASE

Claim 4: A method of generating an animal exhibiting a pathological condition of depression, schizophrenia or Alzheimer's disease, comprising disruption of GNMT gene in the animal by recombination at GNMT gene locus.

Exclusions to patentability: the human body (section 1a of Patents Act)

- 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.



EP 2430038 B1: METHODS AND COMPOSITIONS FOR TREATING NEURODEGENERATIVE DISORDERS AND ALZHEIMER'S DISEASE AND IMPROVING NORMAL MEMORY

Claim 1: An isolated polypeptide consisting of an amino acid sequence RRSLGHPEPLSNGRPQGNSRQVVEQDEEEDEELTLKYGAK (fragment of human presenilin 1)

Claim 4: An isolated polynucleotide consisting of a nucleotide sequence encoding the polypeptide of claim 1.

Claim 7: A method for expressing a polypeptide of claim 1, comprising culturing a recombinant host cell into which a polynucleotide encoding the polypeptide has been introduced.

Exclusions to patentability
section 1b of Patents Act

- Patents shall not be granted for inventions the commercial exploitation of which would be contrary to ordre public or morality.
- The following inventions shall be considered unpatentable:

(1) processes for cloning human beings;

(2) processes for modifying the germ line genetic identity of human beings;

(3) uses of human embryos for industrial or commercial purposes

(4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Patenting of pharmaceuticals

Medical uses in patent law
Supplementary protection certificates

PRH PATENTTI- JA REKISTERIHALLITUS

Patent claims directed to substances or compositions

- Generally, a product must be defined in a patent claim by disclosing its composition or its structural
- in the context of a product claim, stating the use of a product is usually interpreted to mean a product that is suitable for the stated use
  - Claim 1: **Substance X for use as a catalyst in reaction Z**
  - Claim 1 is interpreted to mean substance X suitable for acting as a catalyst in reaction Z
  - Closest prior art D1 describes using substance X is as a dye
  - If X, as disclosed in D1, would be suitable to catalyse reaction Z, then D1 is novelty-destroying for claim 1

First medical use

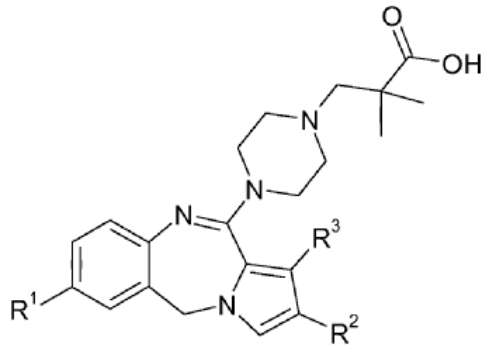
- When a substance or a composition is disclosed for the first time for use in surgery, therapy or diagnostic method practised on the human or animal body, it may be patented for use in this method
  - Claim 1: **Substance X for use as a medicament**
  - Closest prior art is document D1 describing the use of substance X in dyeing fabric
  - If D1 does not disclose the use of X as a medicament, it is not novelty-destroying for claim 1, regardless of whether X is presented in D1 in such a form that would be suitable for medical use

EP 2683719 B1

SUBSTITUTED [(5H-PYRROLO[2,1-c] [1,4]BENZODIAZEPIN-11-YL)PIPERAZIN-1-YL]-2,2-DIMETHYLPROPANOIC ACID COMPOUNDS AS DUAL ACTIVITY H1 INVERSE AGONISTS/5-HT2A ANTAGONISTS

Claim 1:

1. A compound of the formula



where R^1 is chloro or methyl;
R^2 is methyl, ethyl, isopropyl, chloro, bromo, trifluoromethyl, or methylthio; and
R^3 is hydrogen or methoxy;

or a pharmaceutically acceptable salt thereof.

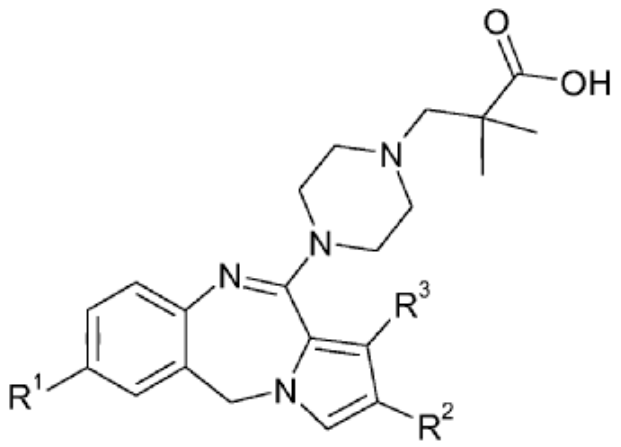
Claim 7: A compound according to claim 1, or a pharmaceutically acceptable salt thereof, for use in therapy

Second or further medical use

- When a substance or a composition is known to already have a medical use, it may still be patentable for other uses in surgery, therapy or diagnostic methods practised on the human or animal body
- Such second or further medical uses must be novel and involve an inventive step compared to the prior use
  - Claim 1**: Substance X for use in the treatment of Alzheimer's disease**
  - Closest prior art is document D1 describing the use of substance X as a medicament in the treatment of asthma
  - If D1 is silent on the use of X in the treatment of Alzheimer's disease, D1 is not novelty-destroying for claim 1

EP 2753366 B1

Claim 1: 1. A compound of the formula



where R^1 is chloro or methyl;
R^2 is methyl, ethyl, isopropyl, chloro, bromo, trifluoromethyl, or methylthio; and
R^3 is hydrogen or methoxy;

or a pharmaceutically acceptable salt thereof.

Claim 7: A compound according to claim 1, or a pharmaceutically acceptable salt thereof, for use in therapy.

Claim 8: A compound according to claim 1, or a pharmaceutically acceptable salt thereof, for use in the treatment of insomnia.

Second or further medical use

- Second/further medical use may be based on
  - Treatment of a different disease
  - Different dosage or administration regime
  - Group of subjects
  - Route of administration

EP 2405749 B1

LOW FREQUENCY GLATIRAMER ACETATE THERAPY

Claim 1: A medicament comprising glatiramer acetate for use in treating a patient who is suffering from relapsing-remitting multiple sclerosis or a patient who has experienced a first clinical episode and is determined to be at high risk of developing clinically-definite multiple sclerosis, wherein the medicament is to be administered in a regimen of three subcutaneous injections of a 40 mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection.

- Prior art disclosed glatiramer acetate for use in treating MS with an administration regimen of daily subcutaneous injections of a 20 mg dose
- The claimed administration regimen was found equally effective as that of prior art in reducing MS relapses.
- The administration regimen according to the invention increased the tolerability of glatiramer acetate treatment by reducing the frequency of immediate post-injection reactions

Supplementary Protection Certificate (SPC)

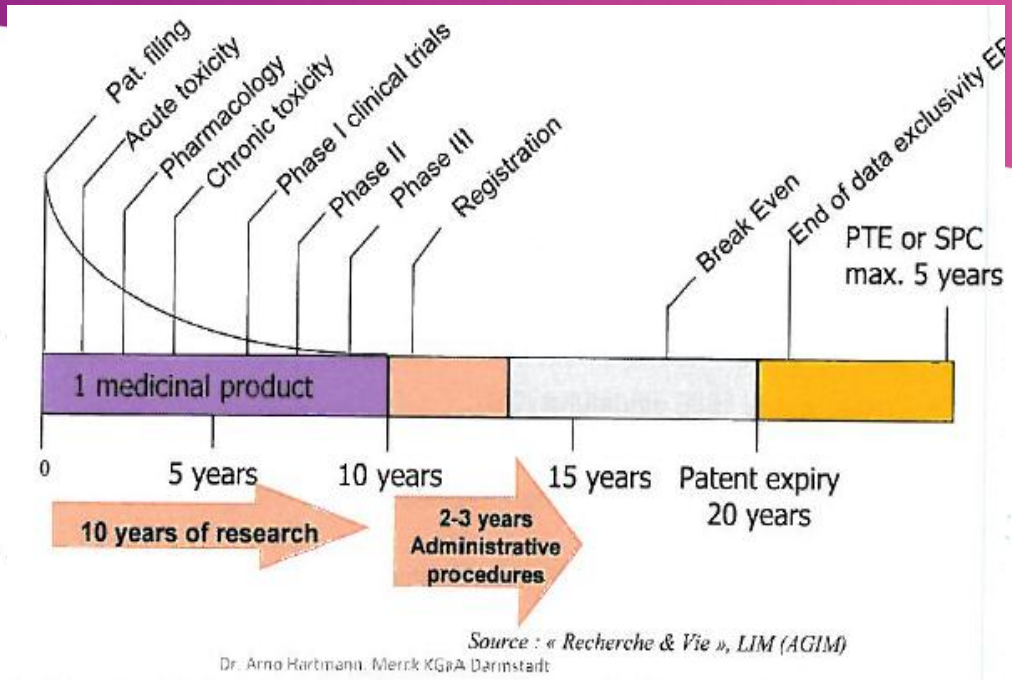
- Maximum 5 year extension to patent's lawful term of 20 years
- Can be obtained for medicinal and plant protection products
- Pediaetric extension
  - Extension of the SPC term by six months
  - paediatric investigation plan (PIP), ie. Compliance

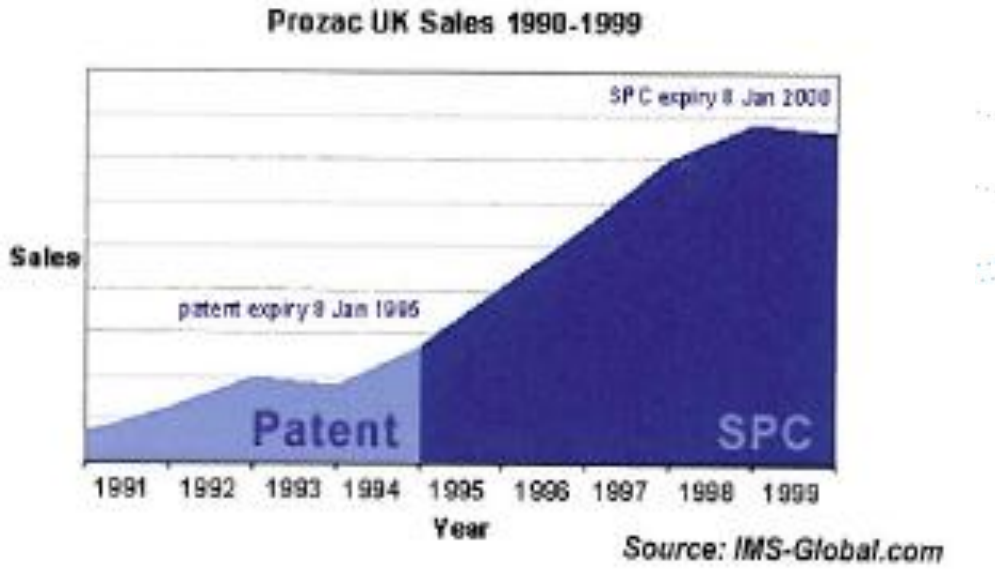
Legislation relating to SPCs

- Regulations
  - Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products (”SPC Regulation”)
  - Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the supplementary protection certificate for plant protection products (”PPC Regulation”)
  - ”Paediatric Regulation (EC) No 1901/2006”
    - amended the original SPC Regulation to allow paediatric extension to medicinal products
  - The regulations are directly applicable in all Member States of the EU
  - Implemented in the national Patents Act and Patents Decree

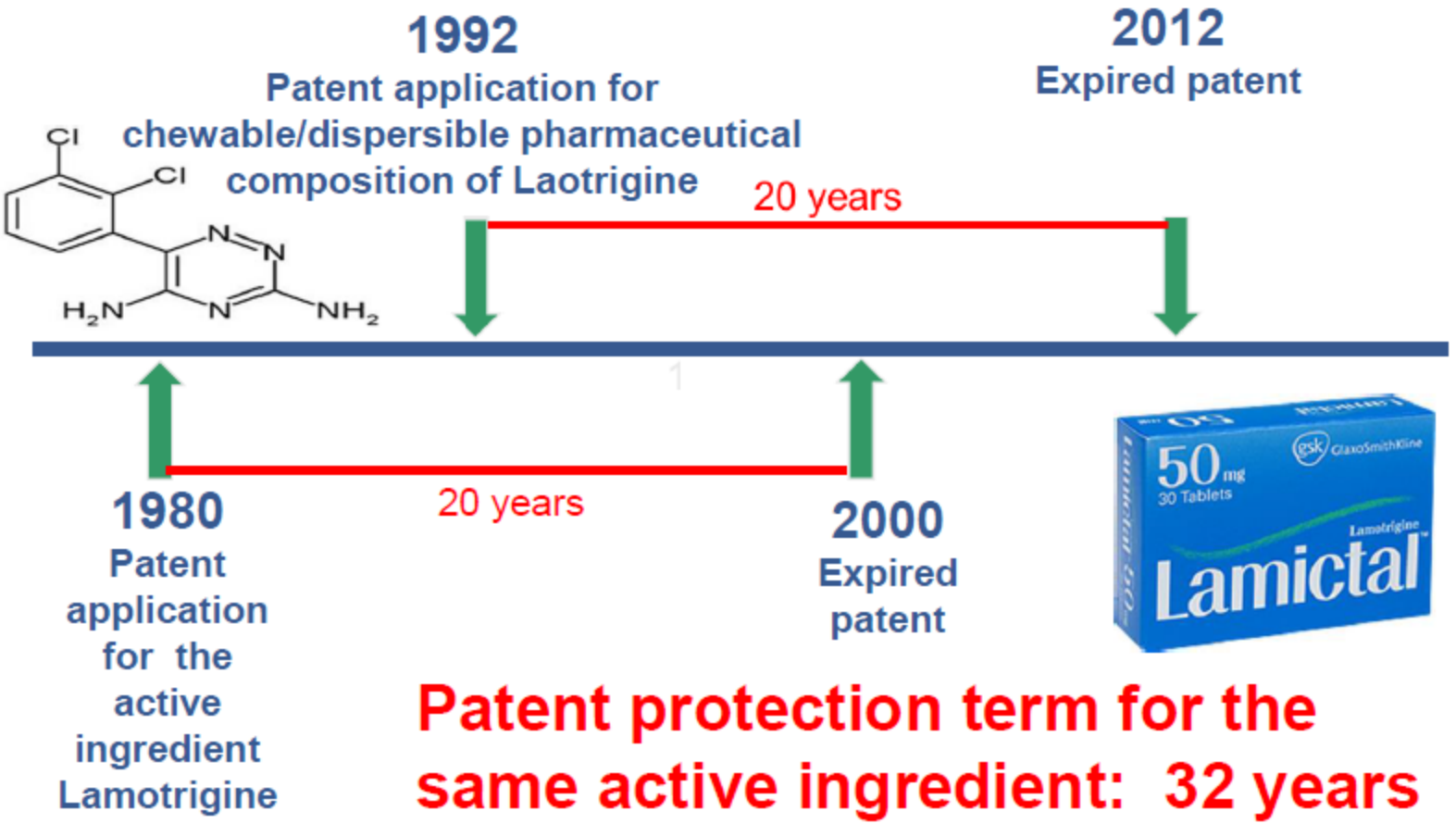
Supplementary Protection Certificate (SPC)

- Innovative pharma companies use IP rights to recoup their R&D investment and compensate for the risks they have assumed
  - It can cost €1 billion or more to develop a new medicine in the period between discovery and marketing, normally a duration of 12 to 13 years.
  - Only around 20% of new products ever recover the cost of development."





Evergreening

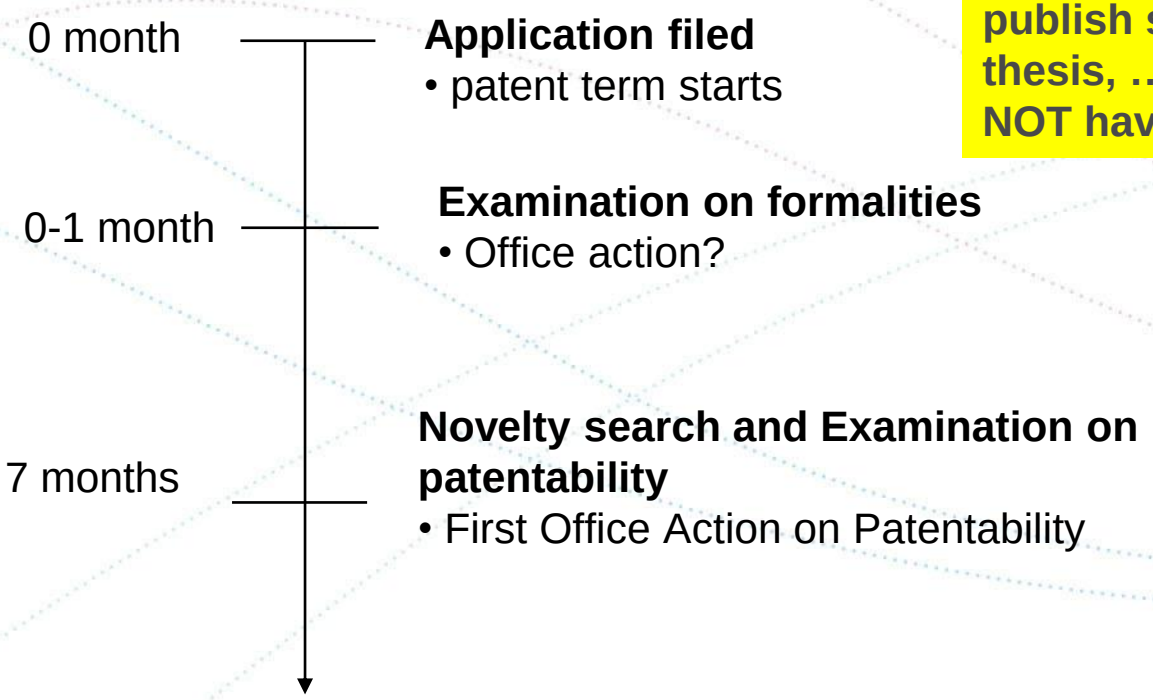


Patenting at home and abroad

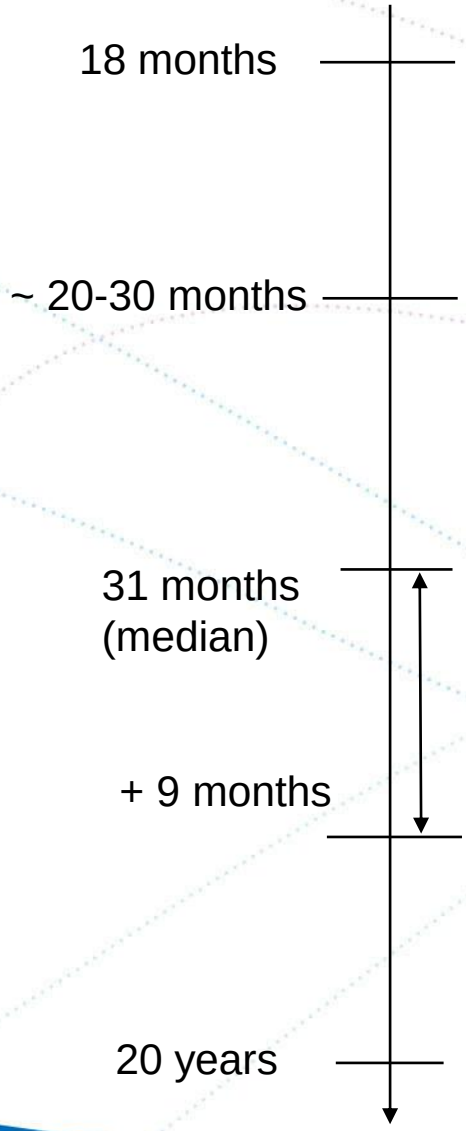
National patent offices
European Patent Convention (EPC)
Patent Cooperation Treaty (PCT)
Unitary Patent System (in EU)

PRH PATENTTI- JA REKISTERIHALLITUS

Timeline at PRH



Remember to file the patent application before you publish scientific paper, thesis, …! Most countries DO NOT have a grace period



Becomes available to public

- via PatInfo database, Espacenet, …
-

Further office actions

- Within 1 year after receiving applicant's reply to first office action

Grant

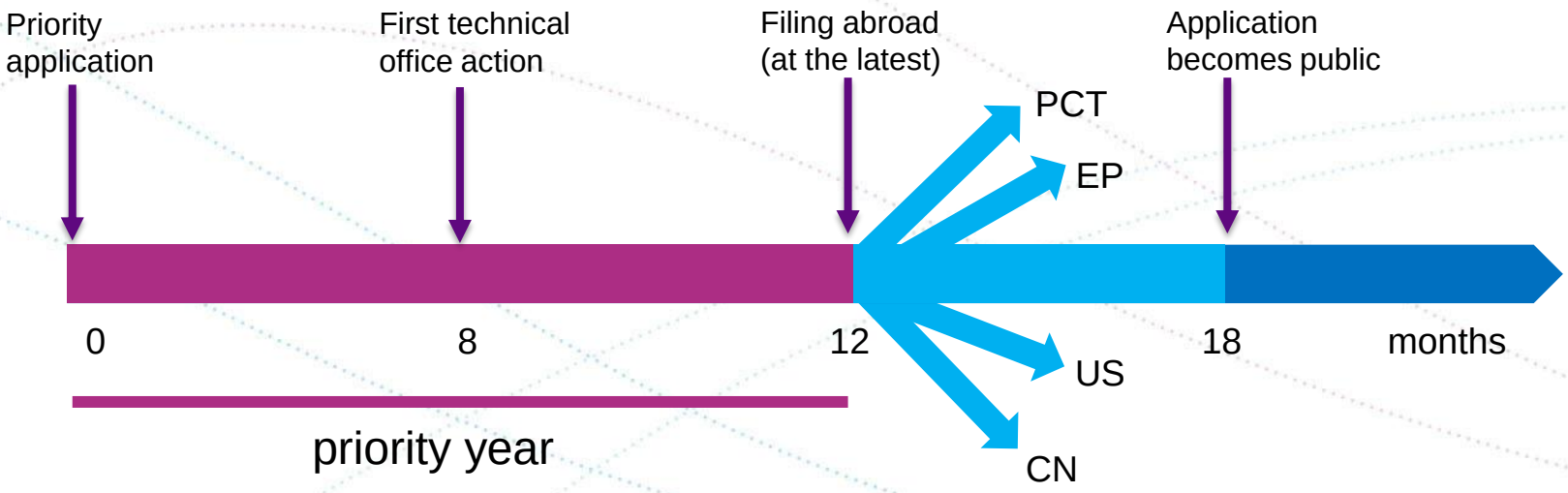
Opposition period

Appeals to Market Court

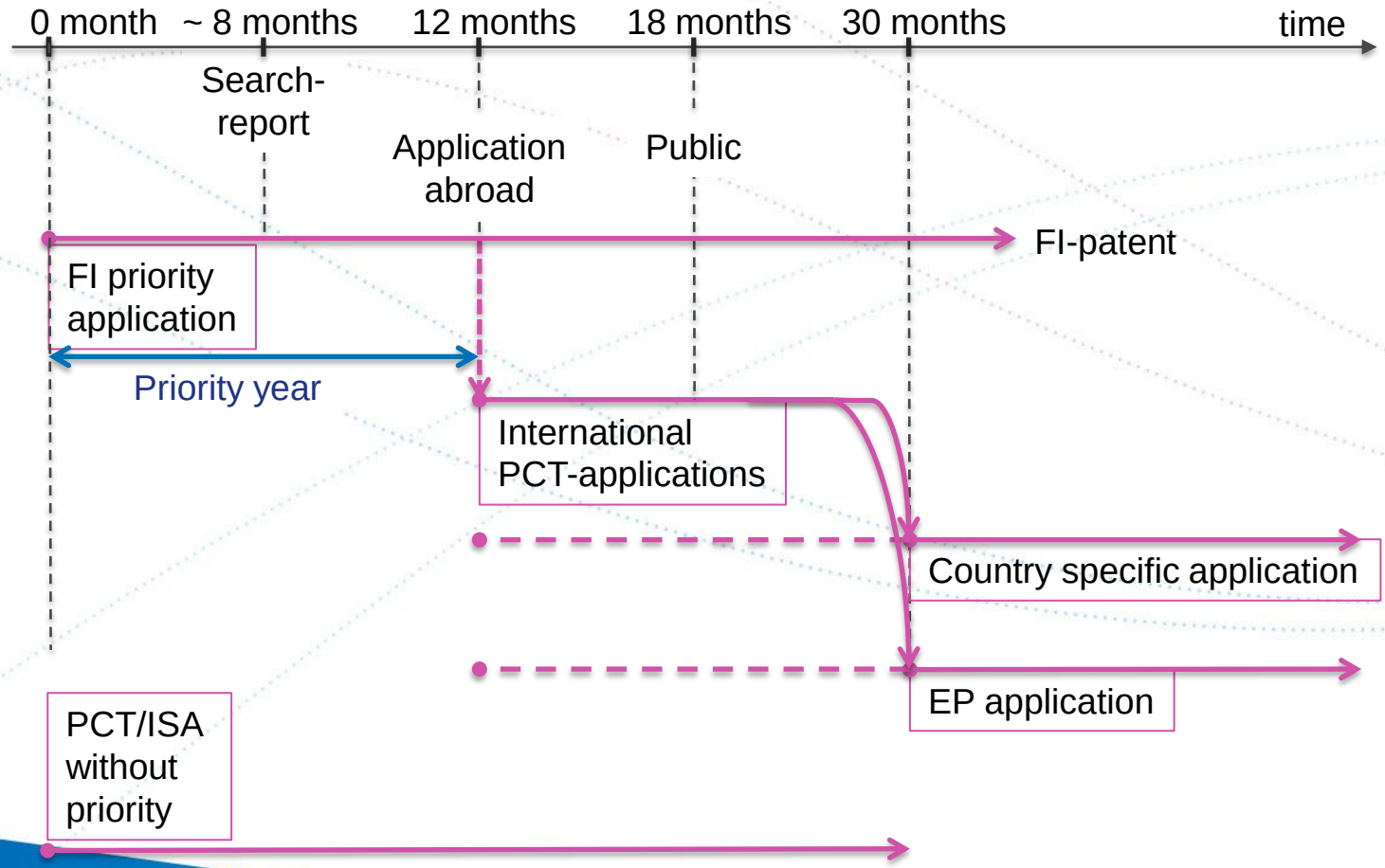
Patentin lapses

- Supplementary Protection Certificates (+5 years max)

Continuing abroad



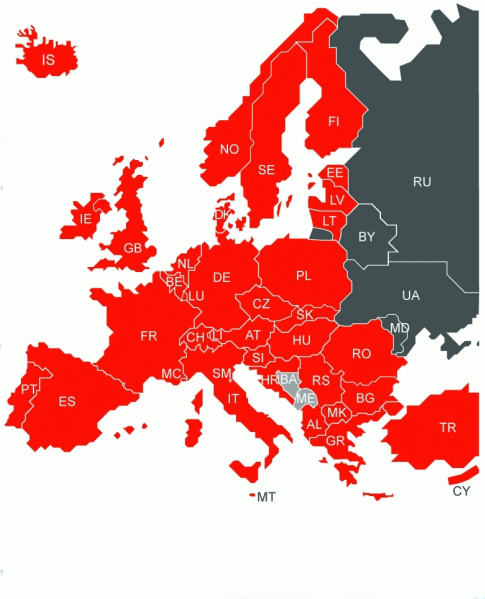
In timeline – PRH as Starting point



FINNISH PATENT AND REGISTRATION OFFICE

Patent Systems

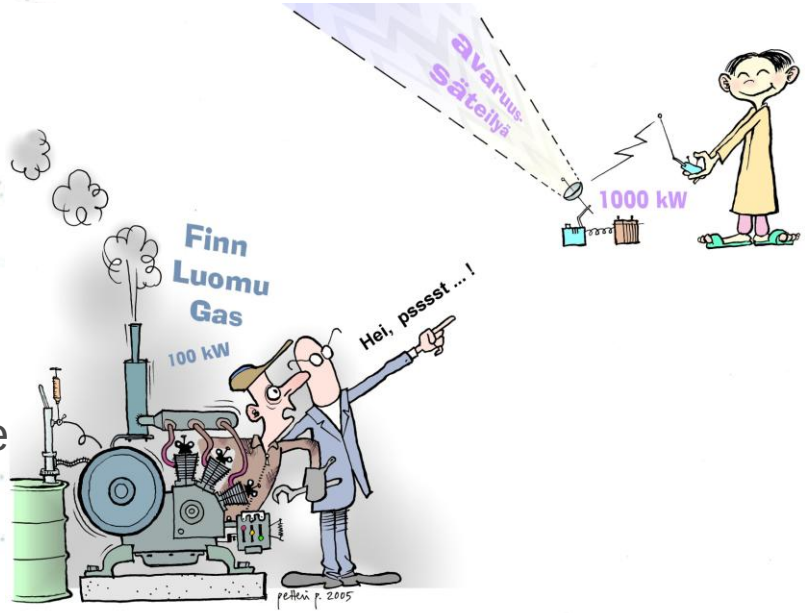
- Patent Cooperation Treaty (PCT)
  - a system for facilitating the application procedure.
  - After international application phase, you can apply for a patent at a national or regional patent office.
  - administered by World Intellectual Property Organisation (WIPO),
- European Patent Convention (EPC) and other regional systems
  - a single application for a European patent
  - a patent validated in selected member states of EPC
- National patent offices
  - USPTO, SIPO, JPO, UKIPO, KIPO, …
- Unitary Patent System (in 2017?)
  - i.e. European patent with a unitary effect
  - single application and a European-wide patent!
  - **Most probably increases heavily the amount of patents rights valid in Finland**



PRH PATENTTI- JA REKISTERIHALLITUS

Patenting abroad

- What, where, how
- Geography: global or local markets
- Competitor types and locations
- Threats of reverse engineering and workaround
- Resources vs. economical gain
- Costs from 30 k€ to 100 k€ depending on the coverage
- Patent application gives time (up to 30 months) to decide how to proceed
- Strength of patent matters (disruptive vs. incremental)



PCT system

- You can start an international patent procedure by filing one single PCT application (international phase), which gives you the option of later file a patent application based in any of the 148 contracting states (national phase)
  - there is no such thing as an "international patent"
- If you do not know exactly in which countries to file, it is a good idea to use the PCT system, as you will have 30 months from the filing date of your first application for consideration.
- Larger costs can be postponed until later.
  - national phase means increased costs, as the application must be translated into the official languages of the national authorities.

European patent

- By filing a single application for a European patent (an EP application) you can obtain a patent in countries which have joined the European Patent Convention (EPC).
  - The convention has been signed by 38 states
- EP applications are processed and EP patents are granted by the European Patent Office (EPO).
- After a European patent has been granted, it must be validated in the EPC countries where you want it to enter into force.
  - Consequently, the European patent is not a supranational patent but a bundle of national patents.

Unitary patent

- In 2017, the European unitary patent will become a new alternative to protect inventions in Europe.
- The classical European patent has to be separately validated in each of the EPC-contracting states, whereas the unitary patent is given unitary effect for the territory of all the states participating in the scheme.
- When it becomes a reality, the unitary patent will be a regional, supranational alternative to the current European patents and national patents;
- The European Patent Office (EPO) will grant both classical European patents and unitary patents.
- The current European patent system will be maintained alongside the unitary patent system.
- In the future, disputes over unitary patents and classical European patents, which are dealt with in national courts at the moment, will be litigated by the Unified Patent Court (UPC).
  - a dispute will be resolved in one go for all the countries that are party to the UPC.
- The Court of First Instance will have central divisions in Paris, London and Munich.
  - local and regional divisions can be set up in those countries that decide to do so.
  - The Court of Appeal will have its seat in Luxembourg.

Patents, business, life

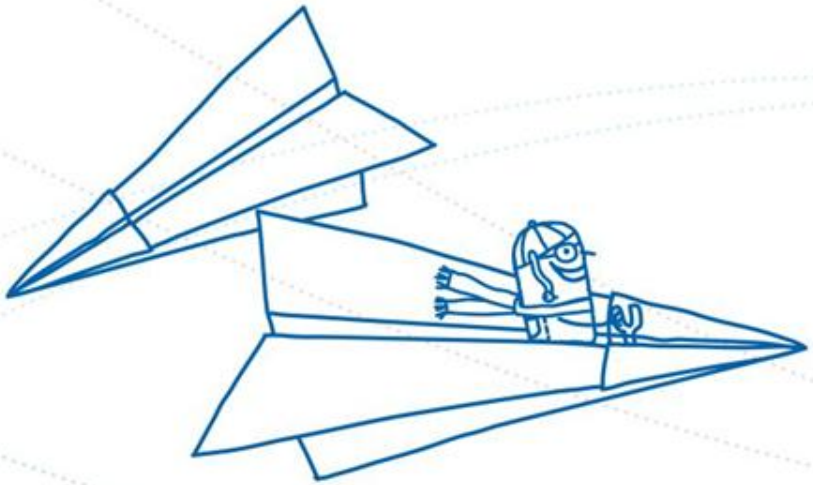
What do you do for living?

PRH PATENTTI- JA REKISTERIHALLITUS

Careers in patenting business

- Patent examiner at Patent Office (civil cervant)
  - *At PRH, over 50 % of examiners (115 in total) have PhD*
  - *Different in-house career paths: team leaders, internal&external lecturing, customer account managers, IT development, international co-operation, etc*
  - *Technical / scientific background forms the basis of the work, patent law and proceedings are learnt*
- Authorized patent attorneys, patent agents (professional reprentatives)
- Patent engineers / managers at companies
- Patent data/search services
- Innovation centers of Universities, Research Institutes, etc
  - *E.g. Helsinki Innovation Services (HIS)*

Questions?



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FINNISH PATENT AND REGISTRATION OFFICE