IP Workshop SaxoCell

Dr. Jörg Smolinski

Kailuweit & Uhlemann
Patentanwälte Partnerschaft mbB
Dresden • Berlin• Leipzig • Bautzen
www.ku-patent.de

Matthias Hoffmann

MAIKOWSKI & NINNEMANN
Patentanwälte Partnerschaft mbB
Berlin • München • Leipzig • Frankfurt/M
www.maikowski-ninnemann.com

Dresden, 16 September 2024

Goals of today

What kind of IP rights exist?

How to get a patent?

How does a patent look like?

How to get a patent?

What is patentable in Biotech/Life Sciences?

How to attack and how to enforce patents?

Ownership of IP

Strategic considerations

Ask Questions Anytime!

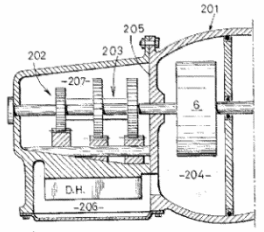
Types of Intellectual Property Rights

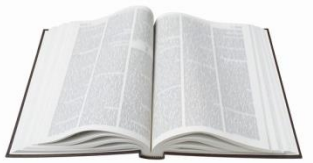
Types of Intellectual Property Rights

IP-Right	Type	Term
Technical IP´s:		
Patent	examined technical IP	20 years
Utility Model	unexamined technical IP	10 years
Non-technical IP´s:		
Trademark	examin. non-tech IP	unlimited
Design	unexamined non-tech. IP	25 years
Copyright	unexamined non-tech. IP	+: 70 years

Overview of intellectual property

Legal right	What for?	How?
Patents	New inventions	Application and examination
Copyright	Original creative or artistic forms	Exists automatically
Trade marks	Distinctive identification of products or services	Use and/or registration
Registered designs	External appearance	Registration
Trade secrets	Valuable information not known to the public	Reasonable efforts to keep secret





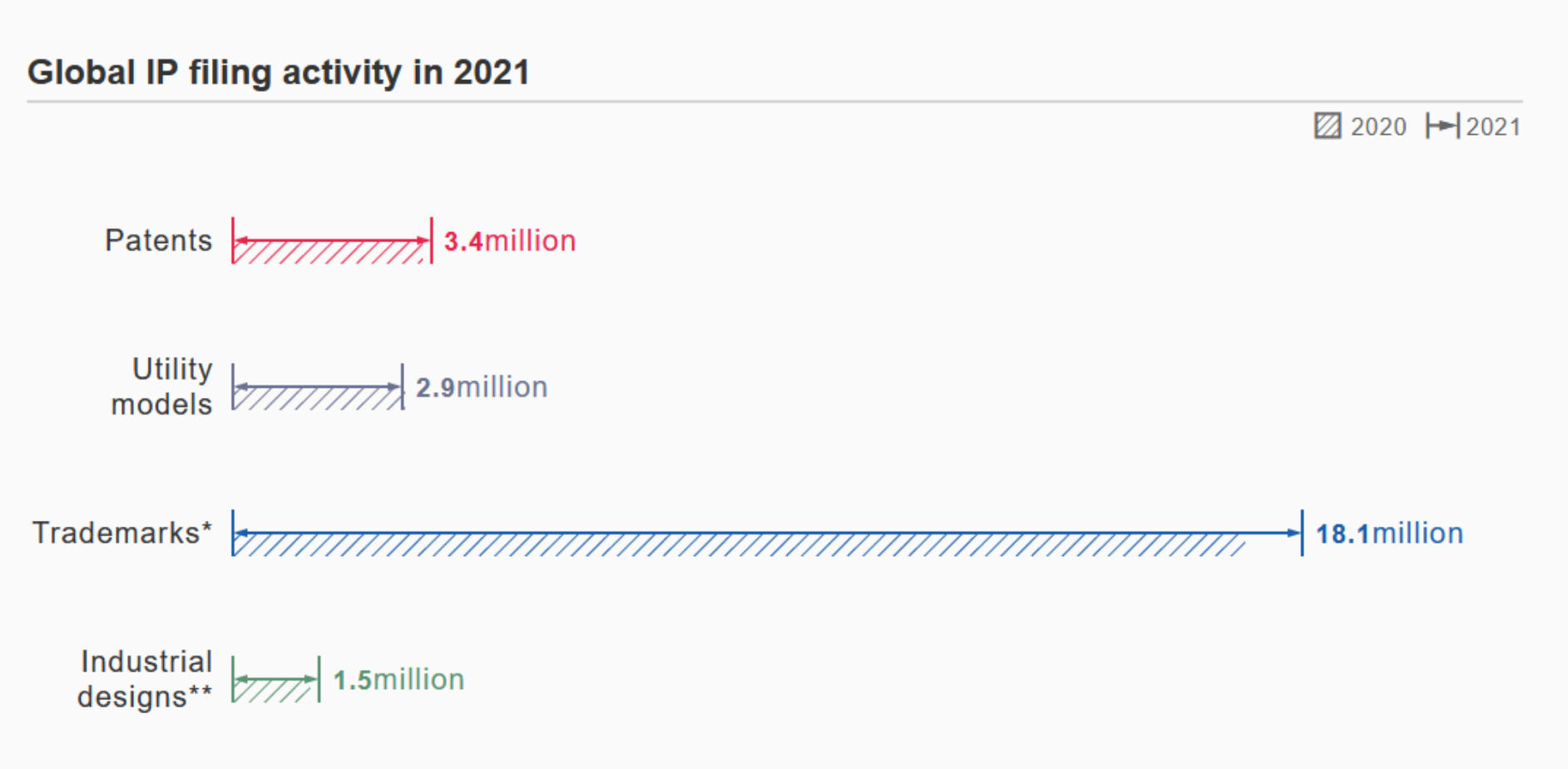
Google

Source: EPO Teaching Kit

Types of Intellectual Property Rights

- Others:
  - Protection of
    - Plant varieties (Sortenschutzgesetz)
    - Semi-conductors (Halbleiterschutzgesetz)

Total Applications Worldwide 2021

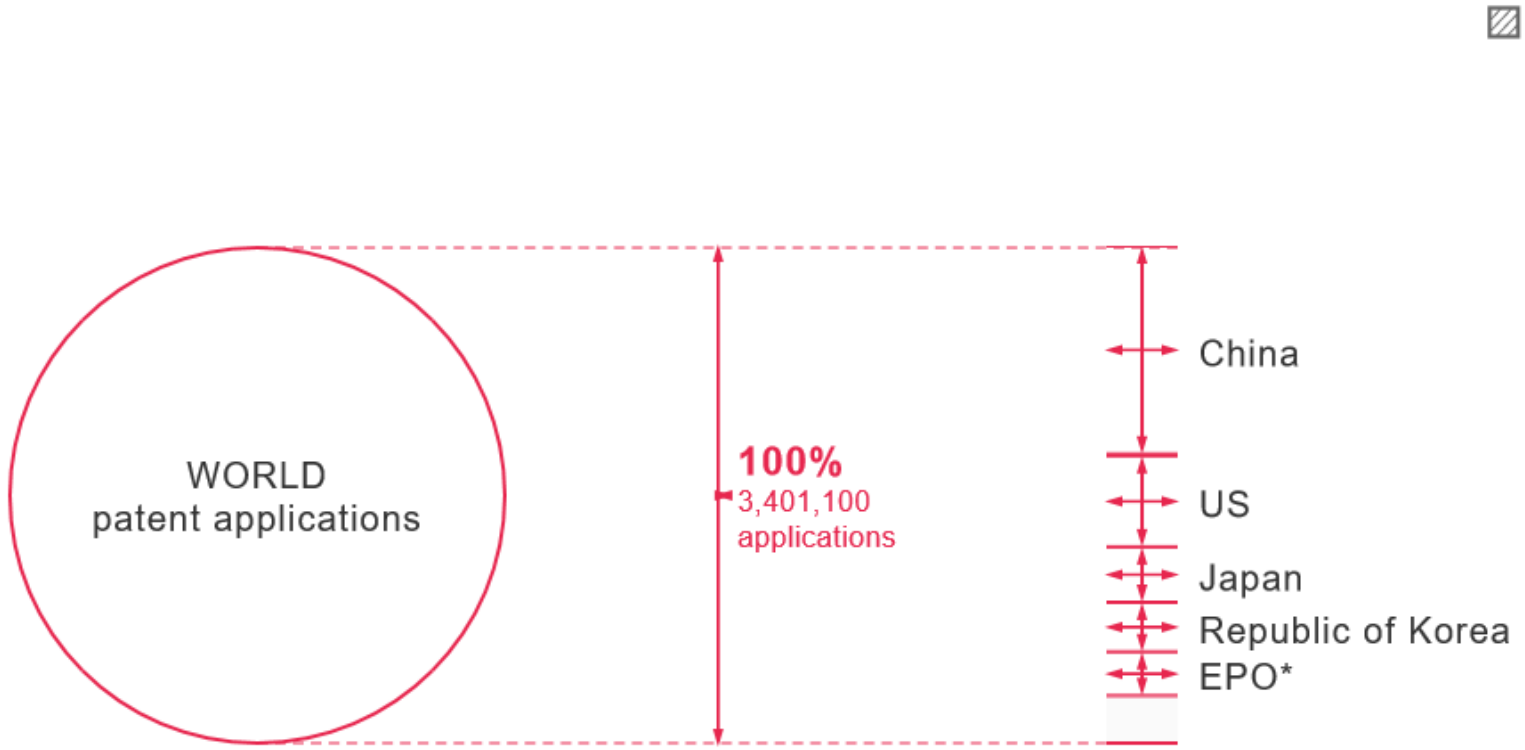


Total No. of Applications: 25.9 million (11.8 million in 2013)

Source: WIPO Statistics Database, February 2023

Total Applications Worldwide 2021

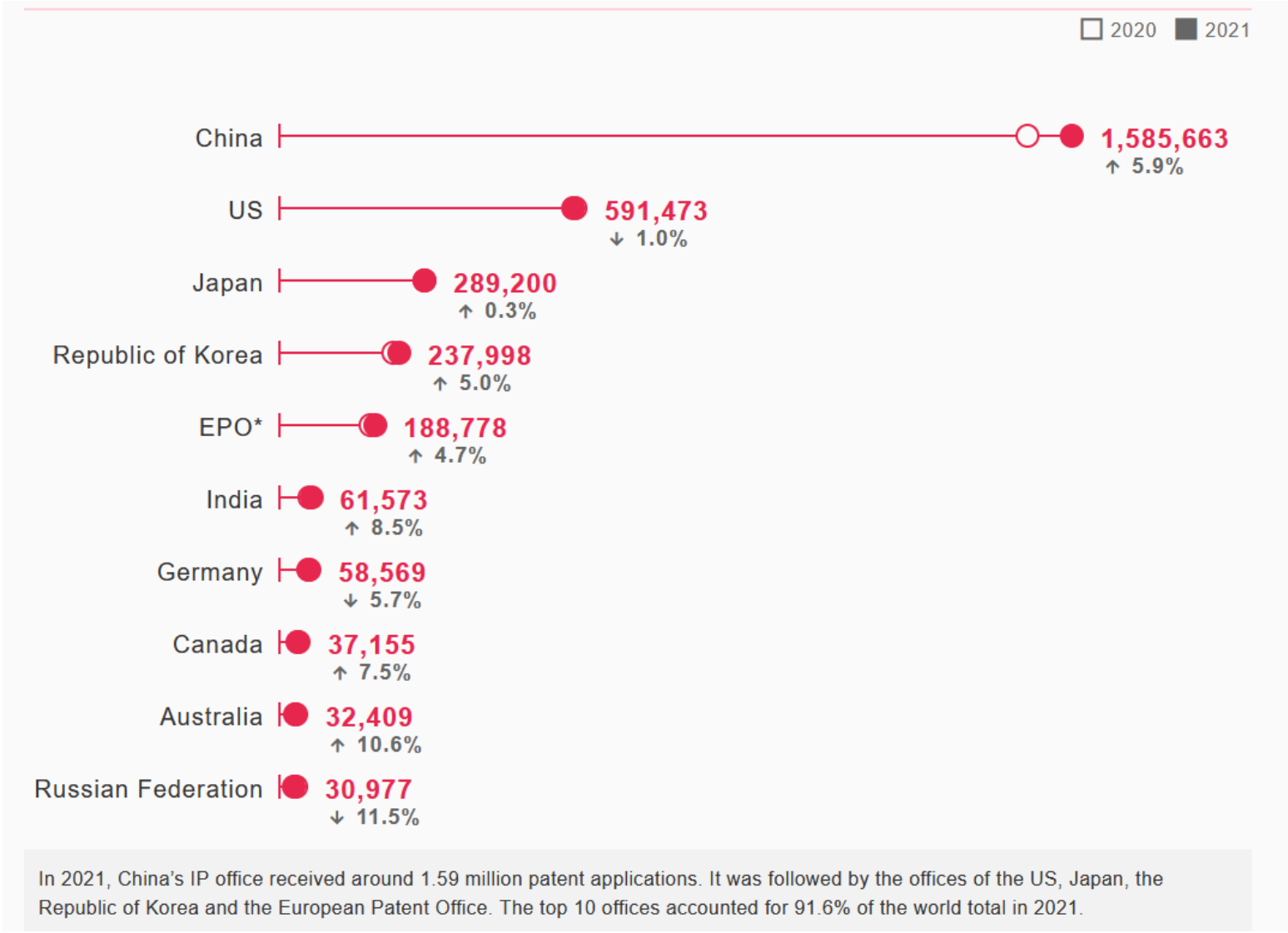
Which IP offices are receiving the most patent applications?



More than 85% of all patent filings in 2021 occurred in the IP offices of China, the US, Japan, the Republic of Korea and the EPO. China accounted for 46.6% of the world total.

Source: WIPO Statistics Database, February 2023

Where was patent activity highest in 2021



In 2021, China's IP office received around 1.59 million patent applications. It was followed by the offices of the US, Japan, the Republic of Korea and the European Patent Office. The top 10 offices accounted for 91.6% of the world total in 2021.

Source: WIPO Statistics Database, February 2023

Some IP found in a mobile phone

Trade marks

- Made by "Nokia"
- Product "N95"
- Software "Symbian", "Java"

Patents

- Data-processing methods
- Semiconductor circuits
- Chemical compounds

Copyrights

- Software code
- Instruction manual
- Ringtone
- …

Trade secrets

?

Designs (some of them registered)

- Outer shape of overall phone
- Arrangement of buttons in oval shape
- Three-dimensional wave shape of buttons
- …

Source: EPO Teaching Kit

Copyright

Works of literature, science and art are protected by copyright law if they are the result of an individual (personal) intellectual creation.

Examples are creations in the areas of:

- Music
- Language (including **Software**)
- Books, PhD thesis,
- Movies, Photos
- Sculptures,
- Paintings….

Copyright

Start of protection:

- once the final form of the work has been completed
- no registration is necessary (**Software** is protected by copyright without registration)

End of protection: 70 years after dead of the creator

Software can only be protected by a patent, if it has a direct technical implication. Thereby, technical principles (not only a concrete form) can be protected, which provides for a much broader protection.

Trademarks


ASPIRIN
Wirkstoff: Acetylsalicylsäure
20 Tabletten N2


kultur
arena


BAYER


Coca-Cola


BMW

Trademarks

What is a trademark?

- Signs that are suitable for distinguishing goods or services of a particular enterprise from that of other companies are eligible for trade mark protection.

- Trademark protection in Germany arises
  - from the entry in the register of the German Patent and Trade Mark Office and is subject to a prior application, or
  - due to intensive use of a sign in the course of trade, or
  - from the fact that a sign is well-known.

Trademarks

Trademark protection for your goods and services

- *Trademarks identify...*
- Trademarks identify goods and services of an enterprise.
- Anyone can file a trademark.
- Trademark protection is available for
  - words,
  - letters,
  - numbers,
  - pictures,
  - 3D-appearance of goods,
  - and even colors and sounds.
- Goods and services grouped in 45 classes (*Nizza classification*)
- Protection for selected goods and services, usually 3 classes

Trademarks

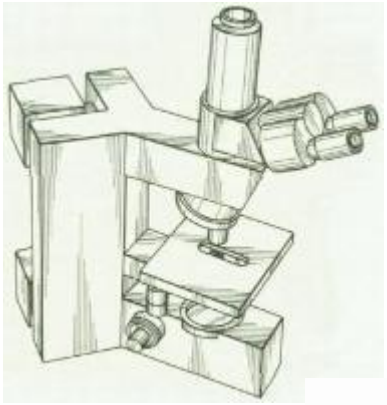
- National Trademarks, e.g. German Trademark
- EU-wide protection by Community Trademark
- International Registration via the World Intellectual Property Organization (WIPO/OMPI)
  - Currently 115 Member staes
- Renewal fee every 10 years.

Design

As a design, a pattern or shape is protected that is new and unique.

Protection of the external appearance (design as color or shape) of two- or three-dimensional objects (for example fabrics, furniture, website etc.)

Product must remains visible during its normal use



Design – General Procedure

- Registration (no examination)
- Areas of protection:
- Germany (DPMA)
- EU (EUIPO)
- international via Hague Agreement Concerning the International Registration of Industrial Designs (WIPO);
- Currently 77 contracting parties
- Individually in each country (extensive and expensive, Design Patent)
- Duration: 25 years,
- Renewal fees to be paid every 5 years

Patents vs. Utility Models

Patents

-Duration 20 Jahre

Utility models

- Duration 10 Jahre

Patents vs. Utility Models

Patents

- Protection of products, substances, materials, manufacturing processes, work processes

Utility models

- Protection of products, materials and substances

Utility Model – Inventive step

- Since 2006, the Federal Court of Justice has equated inventive step in patents and utility models in its case law

- But: different prior art for Utility Model assessment (oral disclosure, prior use only abroad...are excluded)

Why applying for a Utility Model?

- **Advantages**
  - pure registration procedure
  - quickly available (approx. 3 months)
  - Inexpensive
  - limited state of the art compared to patent
  - grace period (6 months)
  - Cost-effective establishment of early filing date for later patent application by means of internal priority
  - utility model application can be split off from a patent application (not from a granted patent!)

Why applying for a utility model?

- **Disadvantages**
  - unexamined property right
  - shorter term of protection
  - no processes/methods protectable

Split off utility model (§ 5 GbmG)

- Independent utility model application for which the seniority of an earlier patent application is claimed
- Seniority of the patent application is decisive for the assessment of protectability, term, renewal fees of the utility model
- IP right already enforceable during the examination stage of the patent

Patents

Patents

- What is a patent?

- Criteria of patentability
  - Invention
  - Novelty
  - Inventive step
  - Computer implemented inventions

- Procedure

- From the invention to the patent application
  - Structure of a patent application
  - Claims and biotechnology inventions

Patents

What is a Patent?

A patent can be considered as a “contract” between the inventor and the State, wherein the State grants protection rights to the inventor in exchange for the disclosure of the invention.

A patent is a temporary limited monopoly, which is granted to the inventor or his successor by the State, for its territory and for the economic use of an invention.

Patents

- **Prevent others** from making, using, offering for sale, selling or importing infringing products or processes **in the country where the patent was granted**
- **Sell these rights** or conclude licensing contracts
- For up to **20 years** from the date of filing of the patent application

The patent does not grant the right to use the invention by the patent owner!

A patent search is indispensable!!!

Source: EPO Teaching Kit

Requirements for patenting

- Patents are granted for **inventions** in all fields of technology, provided that they
  - are **new**,
  - are based on an **inventive step**
  - and are **commercially applicable**.

    (Art. 52 (1) EPC)

Requirements for patenting

- An invention within the meaning of patent law is a **technical teaching**. The prerequisites for this are that the invention
  - gives specific instructions for action,
  - has a practical use,
  - can be realized in a repeatable manner and
  - represents the technical solution of a technical task through technical considerations.
- (Schulte, 8th ed., § 1 para. 18)

Requirements for patenting

- What can be protected?

A **solution** - not just ideas

A **solution** - not a discovery

Invention vs. Discovery

Discovery

The mere discovery of a substance, a technical rule or technical knowledge in nature is a discovery and therefore unpatentable.

The fire was already known in nature, e.g. by resulting from flash fires or volcanic eruptions.

Invention

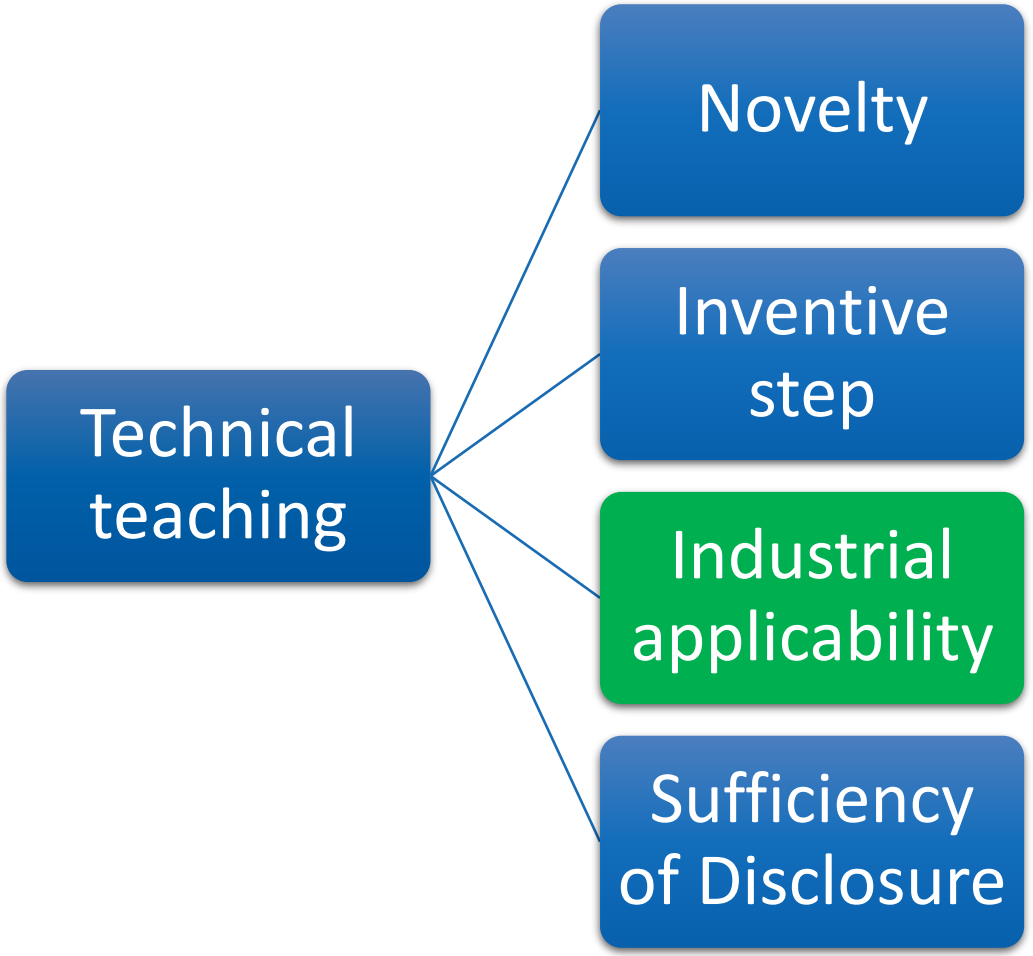
The creation of a technology or a substance whose existence in nature was not known in advance, is considered an invention.

The artificial lighting of fires as by friction or by flintstones and applying the fire on various useful purposes are human inventions.

Requirements for patenting

- Differences to scientific publication:
  - little or no discussion of third-party publications
  - Scientific principle behind the invention of secondary importance
  - Focus on technical applicability
  - Invention must only be practicable but not yet implemented

Criteria of Patentability



Absolute Novelty

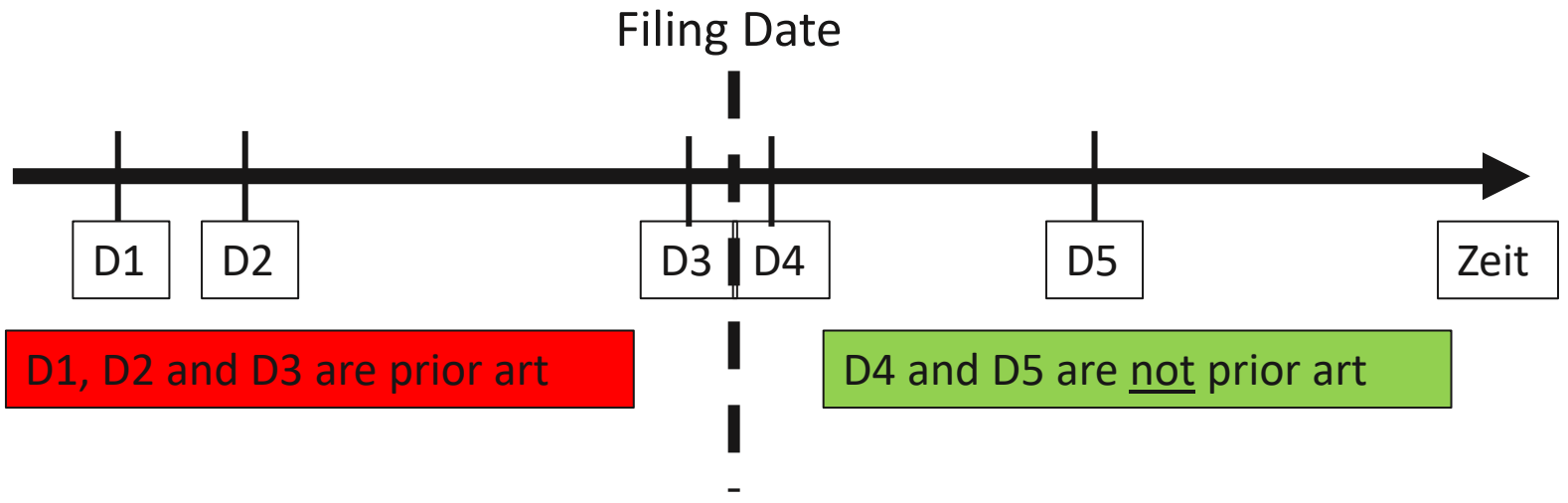
- An invention shall be considered to be **novel** if it does not form part of the prior art.
- The prior art comprises **all knowledge** made available to the public by means of
  - a written or oral description,
  - by public use or **in any other way**,
  - before the date relevant for the priority of the application

Relevant Date: Application date (or priority date)

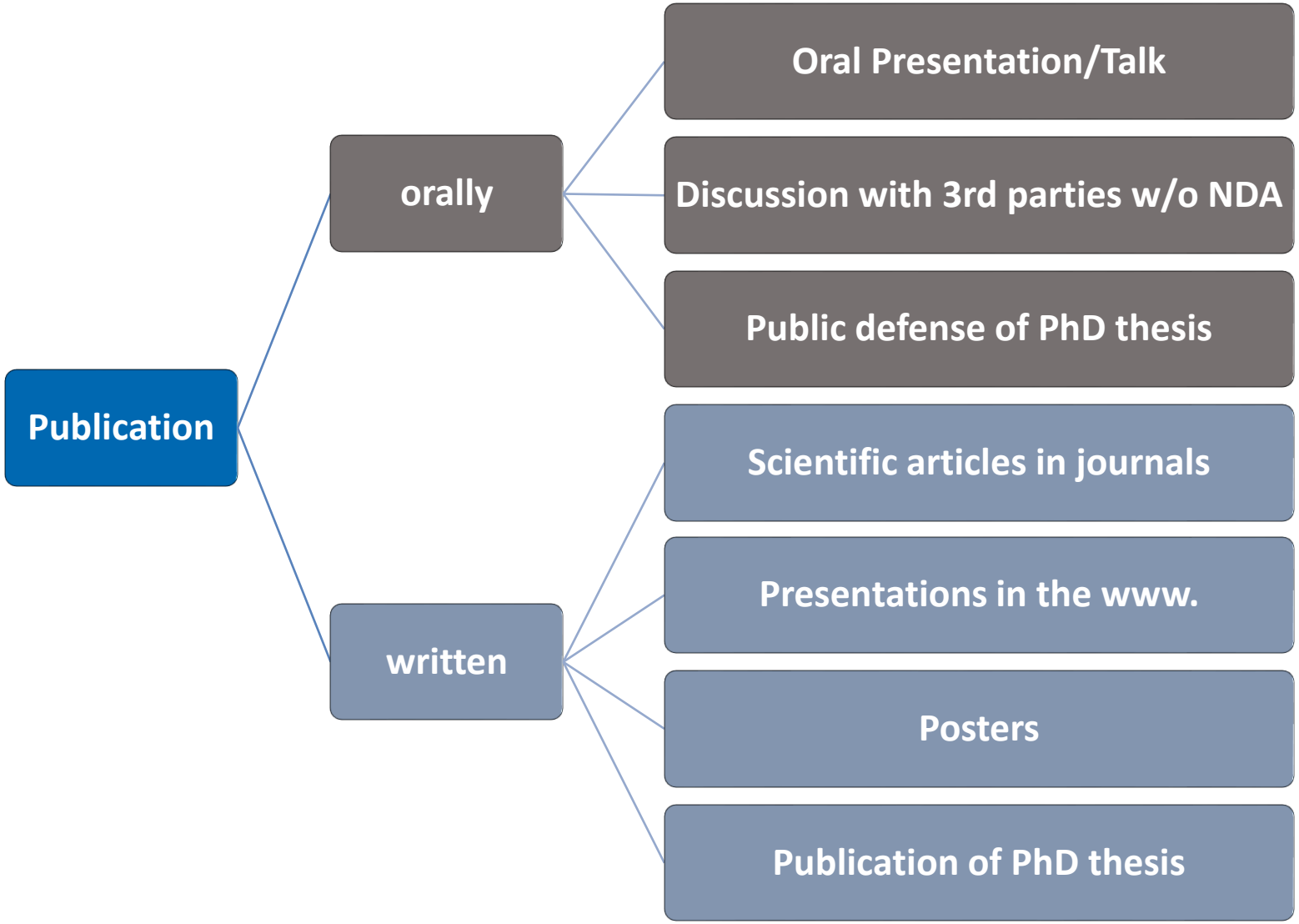
Exceptions: Grace Period in US (1 year)
JP (6 months)
DE (6 months: utility model)

Relevant Date: Filing Date

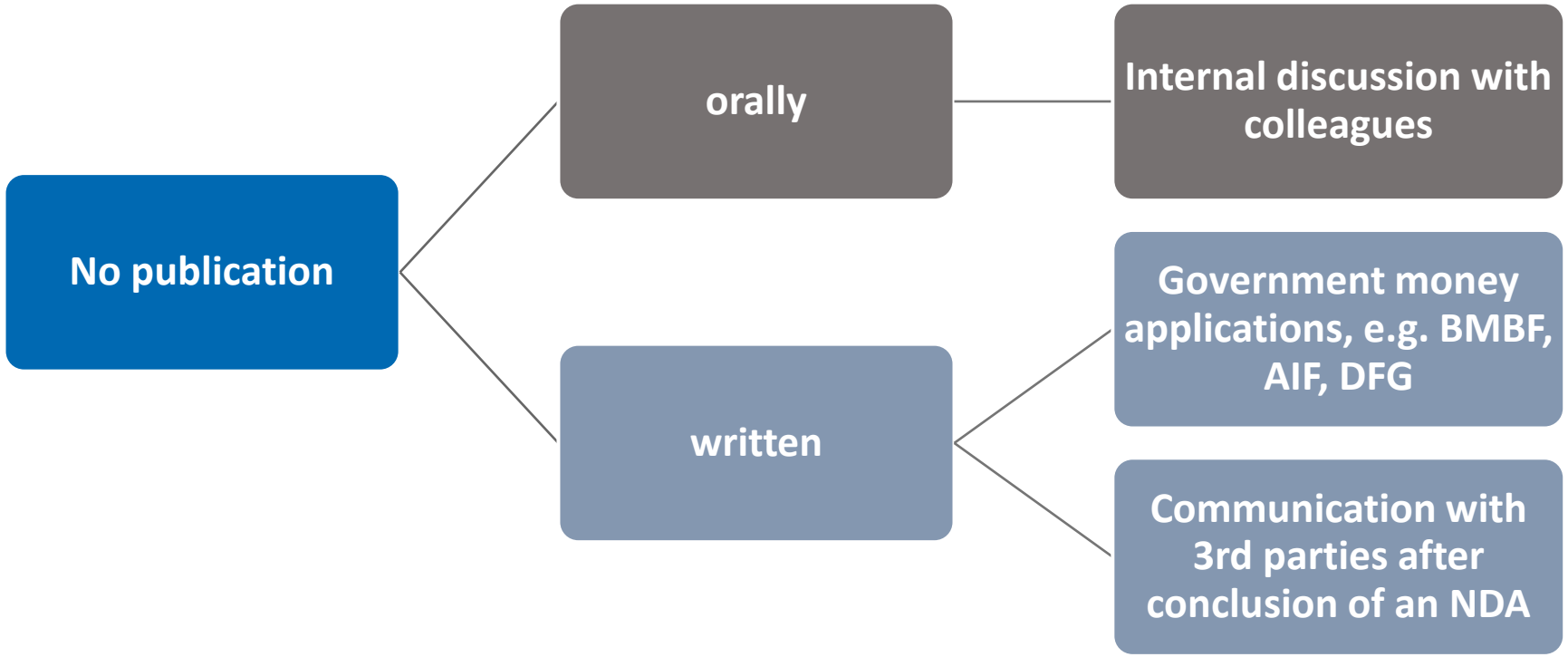
The filing date determines, which prior art documents are to be considered by the patent office during examination of novelty and inventive step.



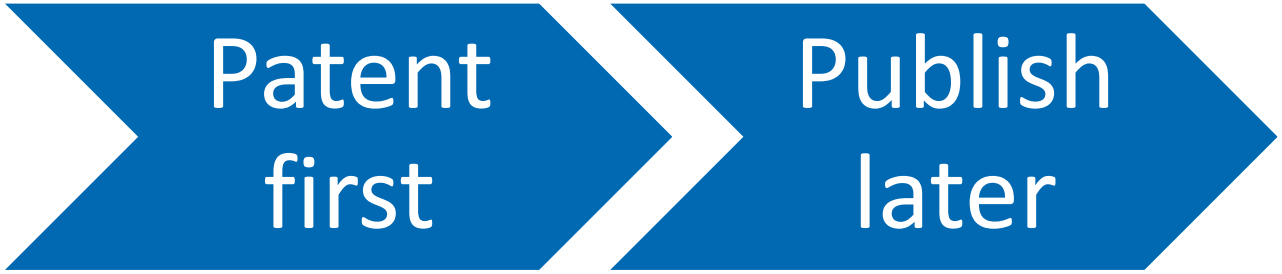
What is „prior art“?



What is „prior art“?



Remember!



Inventive Step

An invention is based on an inventive step:

- if it is **not obvious** to a person skilled in the art
- when considering the known prior art.

The term “not **obvious**" means that:

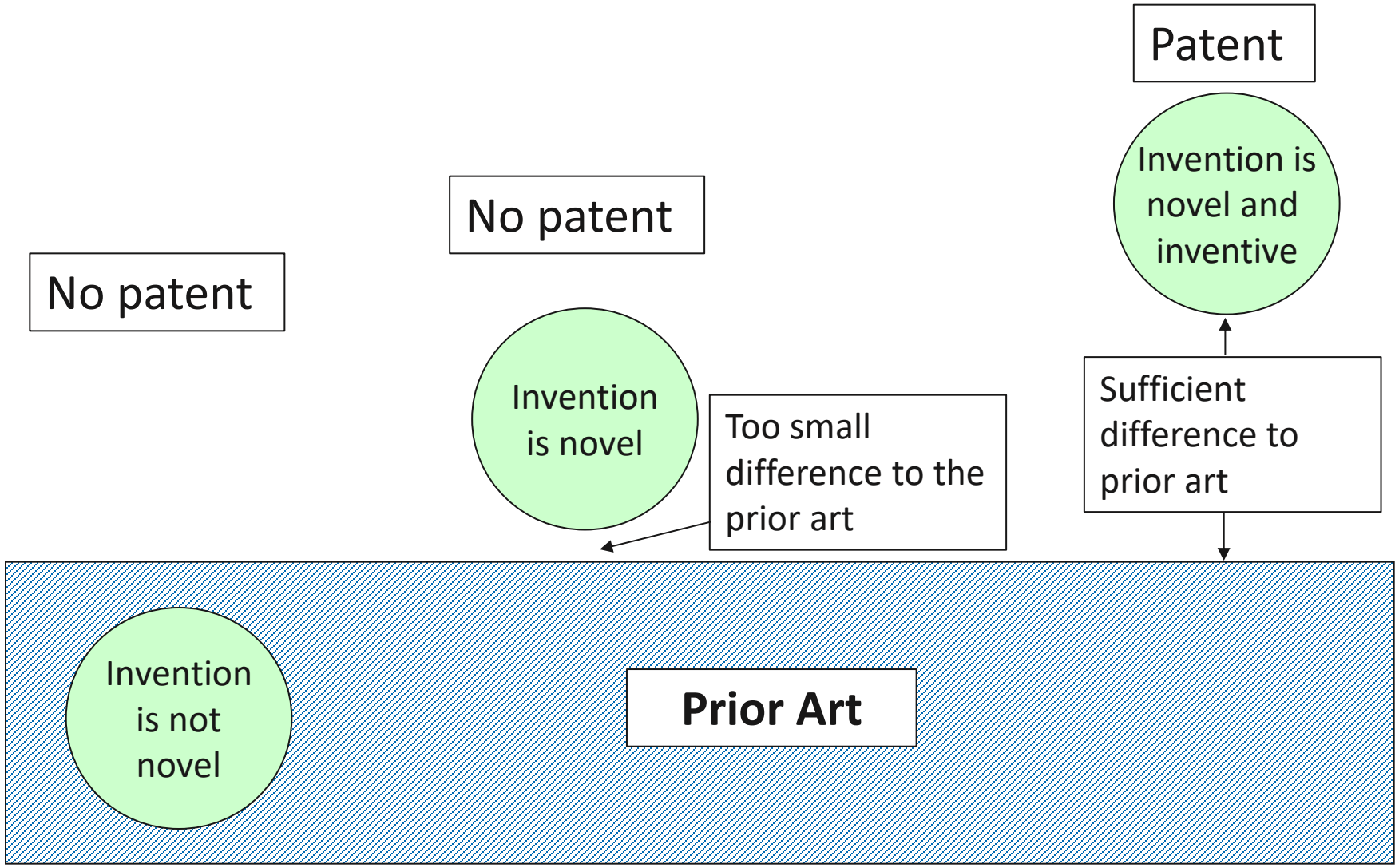
- the invention does go **beyond** the normal progress of technology and
- cannot simply (obviously) be derived from the known prior art.

The invention must be based on a skill or ability beyond that which is to be expected of the person skilled in the art.

There must be something surprising.

The invention must be the result of more than routine experimentation.

Inventive Step



Industrial applicability

An invention is deemed to be industrially applicable if it can be produced or used in any area of industry, including agriculture.

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods are not regarded as inventions which are susceptible of industrial application.

Further requirements for patentability

Sufficient disclosure of the invention

- The patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- All necessary sources for practicing an invention must be described clearly and sufficiently, reproducibility must be ensured.

Further requirements for patentability

→ For patents claiming microorganisms, cells and microbiological processes it is not always possible to fulfill the criterion of the sufficiency of disclosure by a verbal description, e.g. if the

- microorganism or cell is not commercially available for anybody (e.g. own lab stem etc.) or
- isolation of the microorganism or cell from natural sources is not reproducible,
- production of the microorganism or cell is not reproducible (e.g. hybridoma)

Solution: **Deposit for patent purposes, e.g. according to §34(8) PatG, BioMatHintV (biomaterial deposit regulation)**

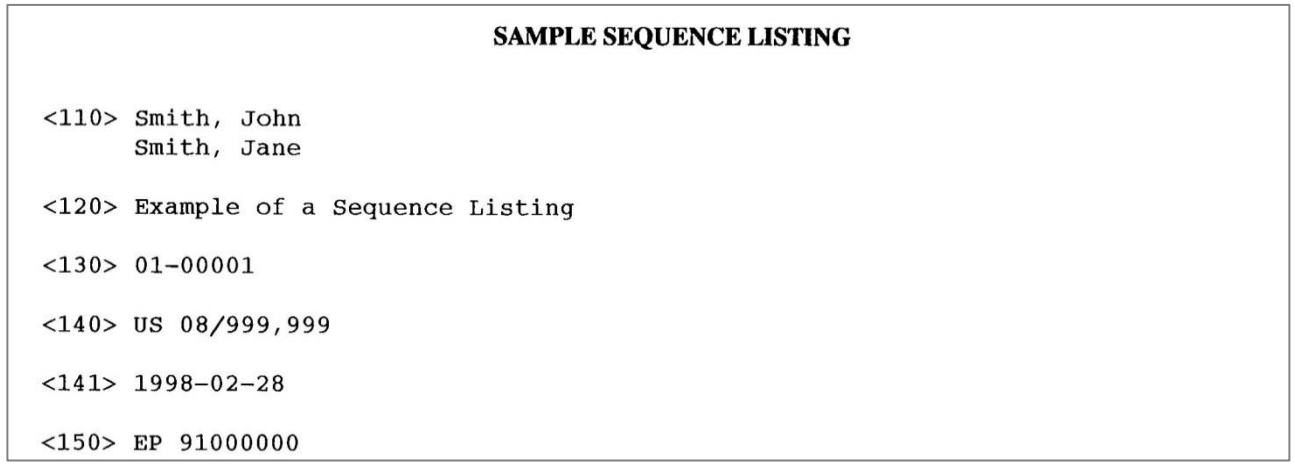
Further requirements for patentability

Proteins and nucleic acids:

- Sequences must be presented in a standardized sequence listing
- Deposit, if production is not reproducible

e.g.

- Antibody w/o known sequence → Deposit of the hybridoma
- Plasmid w/o known sequence
- Characterization of the structure of proteins (optional)



SAMPLE SEQUENCE LISTING

<110> Smith, John
Smith, Jane

<120> Example of a Sequence Listing

<130> 01-00001

<140> US 08/999,999

<141> 1998-02-28

<150> EP 91000000

Exceptions from Patentability

The following in particular shall **not** be regarded as (technical) 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;

- only “as such”.

Exceptions from Patentability

No patents granted for:

- Inventions that are contrary to public order or morality (extremely rare)

- Plant varieties (⊳ Law for protection of plant varieties)
- Animal varieties

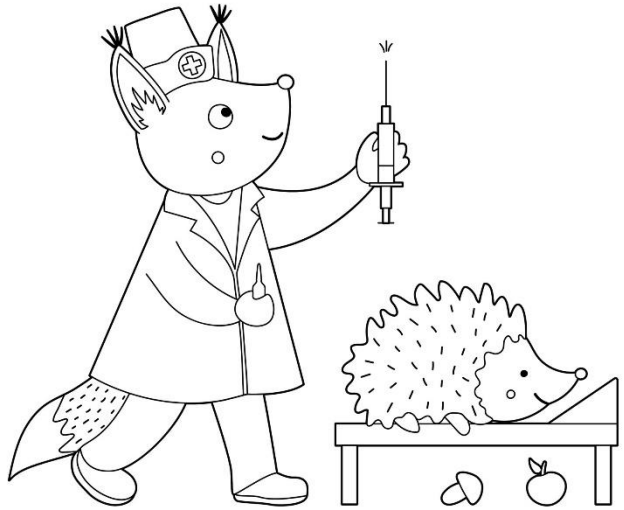
- Essentially biological processes for the production of plants or animals (= conventional breeding).

  - **This provision shall not apply to microbiological processes or the products thereof.**

Exceptions from Patentability

No patents granted for:

- Surgical Methods (per se)
- Therapeutical Methods (per se)
- Diagnostic Methods (per se)



- if applied to the human or animal body

  (▷ Doctors work shall not be interfered with)

  (Exception: US)

Exceptions from patentability

§1a (1) PatG

The human body at the various stages of its formation and development, including germ cells, and the simple discovery of one of its components, ... can not be a patentable invention

Exceptions of the Effect of a Patent

The effects of a patent shall not extend to:

1. Private and non-commercial acts
2. Experiments

2a. Use of biological material for the purposes of breeding, discovering, and developing a new plant variety

2b. Studies and experiments made to obtain approval according to current drug law regulations

3. Direct preparation of medicaments in a pharmacy according to doctors prescription

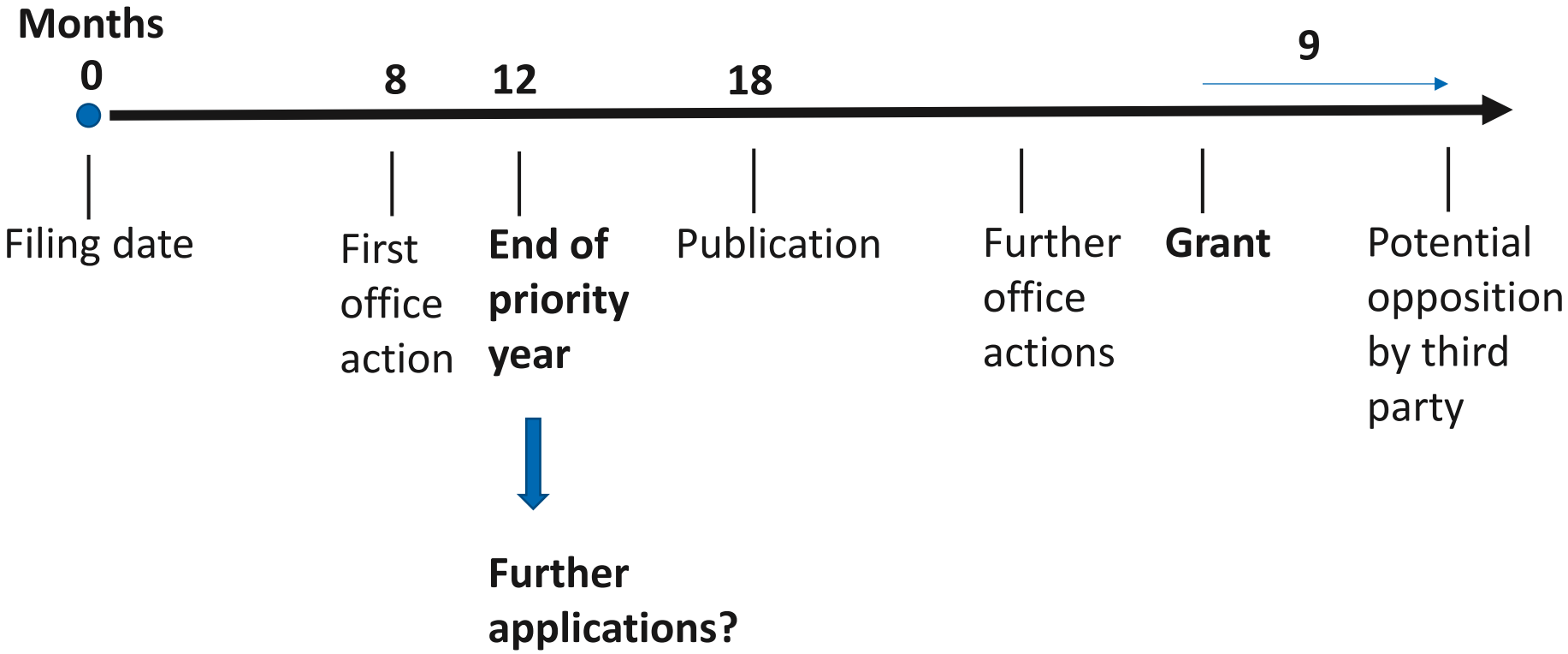
4. …

Procedure of patenting and filing tactics

Procedure of a patent application

- Numerous possibilities
- Rigid deadlines that must not be missed, and which often incur costs for the next step to be carried out if they expire
- Patent application and development ideally run in parallel
- A patent application may not be supplemented once filed with an PTO
- 12-month priority period within which one or more subsequent applications can be filed

Procedure of a patent application



Priority Right

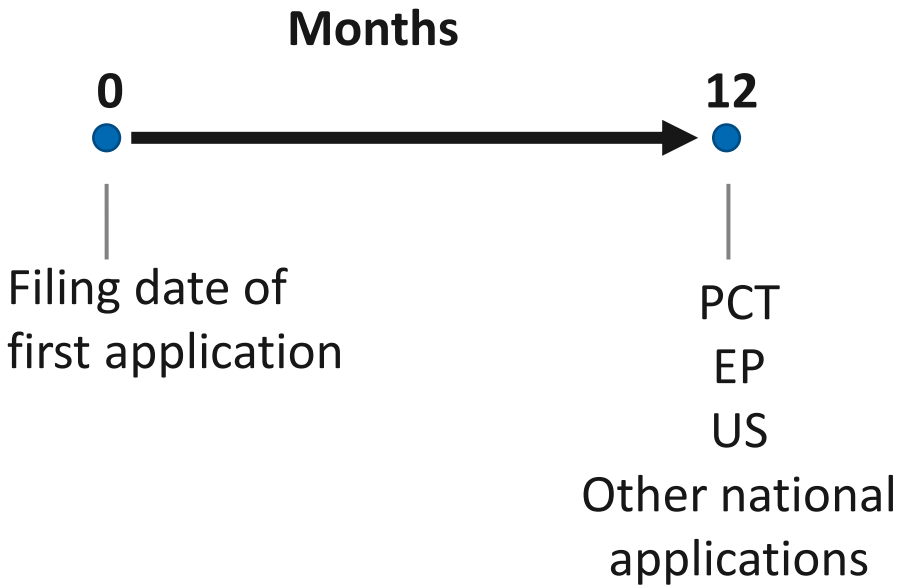
(1) Everybody, who has filed an application for a patent (etc.) in (almost) any State can claim the priority thereof within **twelve months** for the **same** invention.

(2) Multiple Priorities originating in different countries can be claimed.

(3) Any part of previous application can be the basis for priority: claims, description, drawings (whole contents approach)

Legal basis: Paris Convention
National (DE), regional (EP) and international (PCT) laws

Priority Right – Timeline



Priority Term: 12 months

Priority Right – Tactics

- Patent applications cannot be supplemented once filed with a PTO
- New aspects = new application

Priority Right

- Useful for further test results
- Useful for inserting further delimitation options compared to the state of the art
- Caution: Loss of priority if independent claim contains features not included in original application

Remember

- File Subsequent Application(s)
- within 12 months
- after first Application.

Term of a Patent

1 Year	Priority Year
+ 20 Years	Usual Patent Term (beginning with the Filing Date)
+ 5 Years	Supplementary Protection Certificate (SPC) (Schutzzertifikat)
26 Years	Maximum Protection

Registration tactics

- National patent applications (e.g. Switzerland, Germany, France, USA, Australia)
- Regional patent applications (e.g. European patent, Eurasian patent)
- International patent application under the Patent Cooperation Treaty (PCT)

Where?

German patent and trademark office (DPMA)

Deutsches
Patent- und Markenamt

Munich (subsides in Jena and Berlin)

Patents
Utility models
Trademarks
Designs

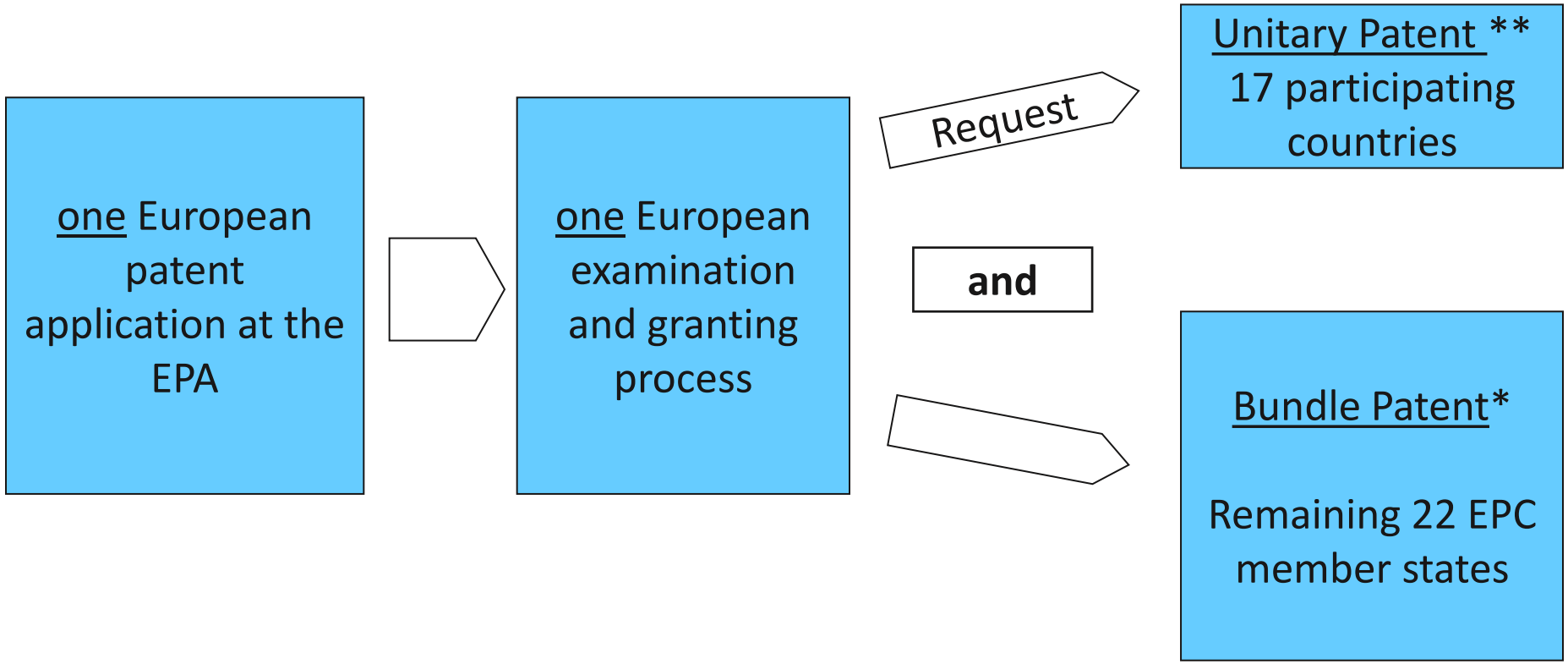
with effect for Germany
www.dpma.de

Where?

European patent

- 38 contracting states
- 1 Extension state Bosnia and Herzegovina (BA)
- Recognition in Morocco, Tunisia and Moldova through validation

Where?



* Validation in the different national states by payment of respective official fees and fulfillment of national requirements, i.e. translation of the claims and/or the entire patent specification under certain circumstances

** Request and 1 full translation within innerhalb 1 month after grant

Where?

✓ Initial Coverage: 17 Countries (EU member states with ratified UPCA)

Austria	Estonia	Italy	Malta	Sweden
Belgium	Finland	Latvia	Netherlands	
Bulgaria	France	Lithuania	Portugal	
Denmark	Germany	Luxembourg	Slovenia	

✓ 7 further EU member states have signed the UPCA and its ratification is therefore likely

Cyprus	Greece	Ireland	Slovakia
Czech Republic	Hungary	Romania	

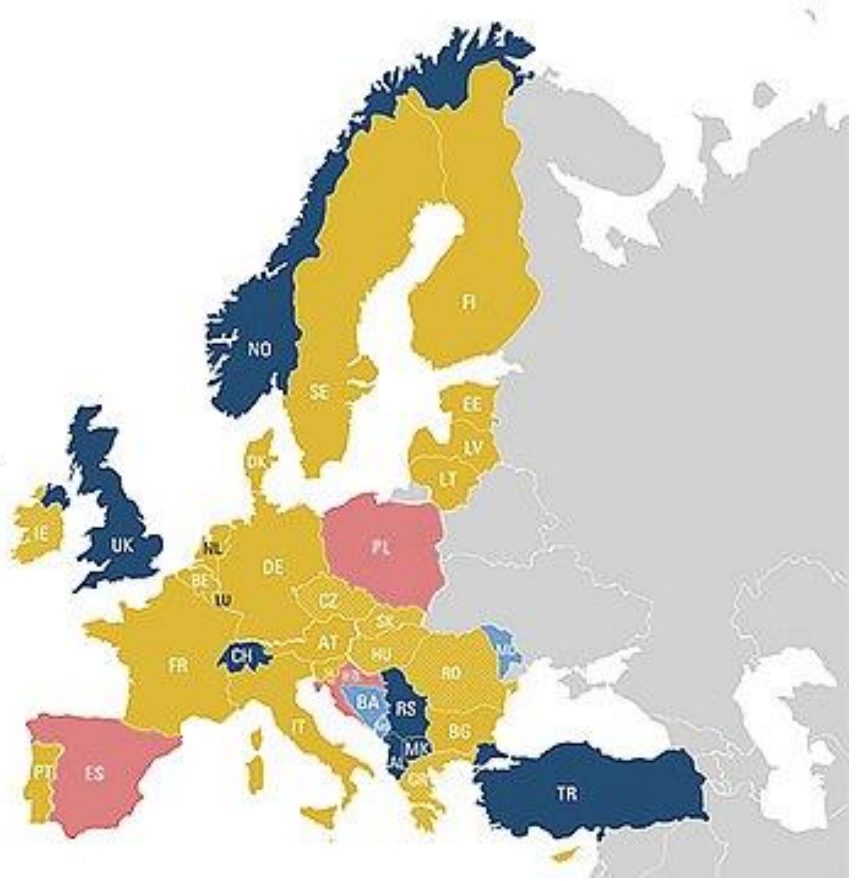
✗ EU member states not participating in Unitary Patent Package

Spain	Poland	Croatia

✗ Other European Patent Convention countries (no participation possible, not in EU)

United Kingdom	Albania	Macedonia	San Marino
Turkey	Iceland	Monaco	Serbia
Switzerland	Liechtenstein	Norway	

Graphic developed by COHAUSZ & FLORACK



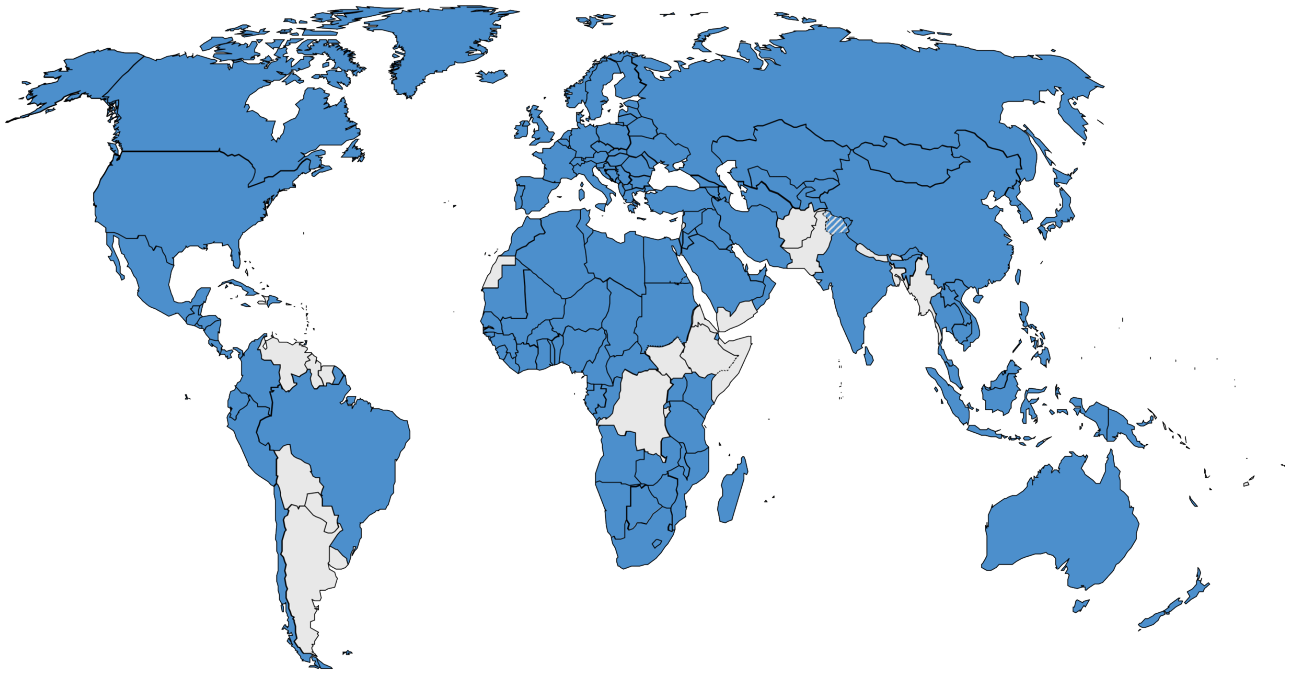
Where?

OMPI/WIPO

Headquarter: Genf

- International patent applications according to PCT (Patent Cooperation Treaty)
- Preliminary securing a patent application
- Up to 30/31 months
- 157 member states on 30th September 2023

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

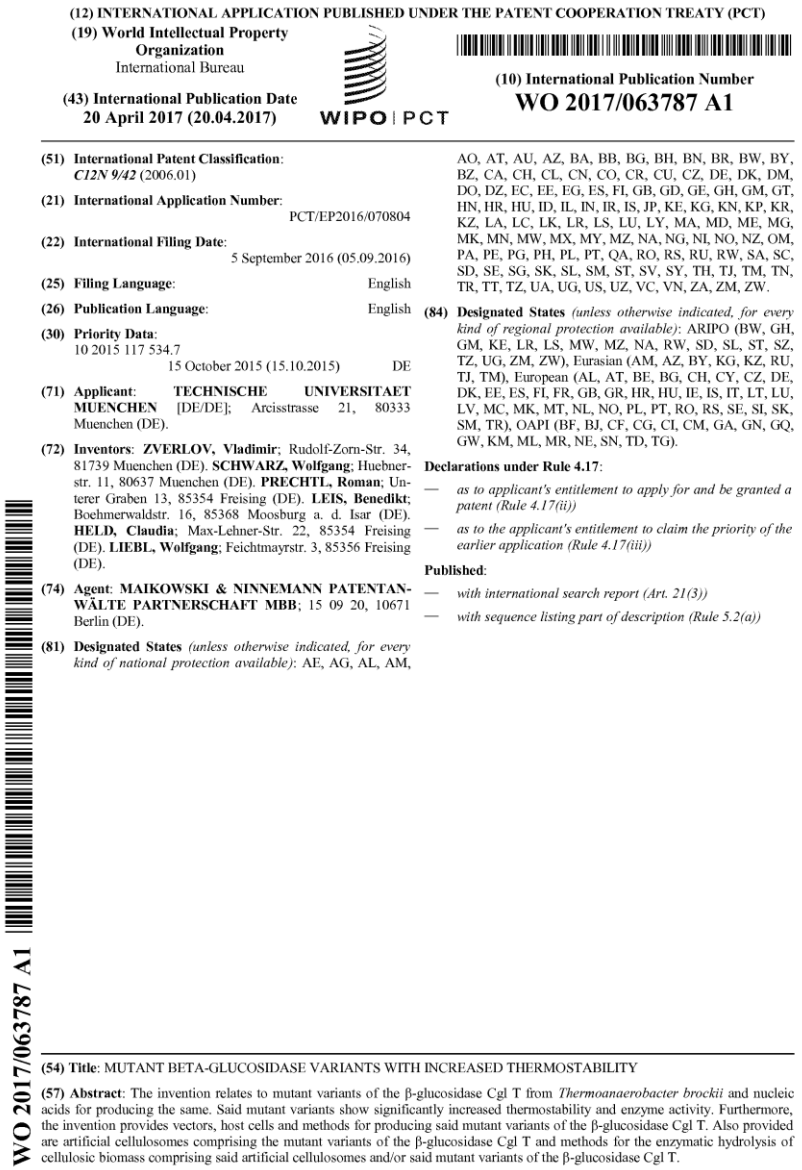


Patents

From the invention to the patent application

Structure of a patent application

What does a patent look like?



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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 April 2017 (20.04.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/063787 A1

(51) International Patent Classification:
C12N 9/42 (2006.01)

(21) International Application Number:
PCT/EP2016/070804

(22) International Filing Date:
5 September 2016 (05.09.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10 2015 117 534.7
15 October 2015 (15.10.2015) DE

(71) Applicant: **TECHNISCHE UNIVERSITAET MUENCHEN** [DE/DE]; Arcisstrasse 21, 80333 Muenchen (DE).

(72) Inventors: **ZVERLOV, Vladimir**; Rudolf-Zorn-Str. 34, 81739 Muenchen (DE). **SCHWARZ, Wolfgang**; Huebnerstr. 11, 80637 Muenchen (DE). **PRECHTL, Roman**; Unterer Graben 13, 85354 Freising (DE). **LEIS, Benedikt**; Boehmerwaldstr. 16, 85368 Moosburg a. d. Isar (DE). **HELD, Claudia**; Max-Lehner-Str. 22, 85354 Freising (DE). **LIEBL, Wolfgang**; Feichtmayrstr. 3, 85356 Freising (DE).

(74) Agent: **MAIKOWSKI & NINNEMANN PATENTANWÄLTE PARTNERSCHAFT MBB**; 15 09 20, 10671 Berlin (DE).

(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, BN, 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, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

— *with sequence listing part of description (Rule 5.2(a))*

WO 2017/063787 A1

(54) Title: MUTANT BETA-GLUCOSIDASE VARIANTS WITH INCREASED THERMOSTABILITY

(57) Abstract: The invention relates to mutant variants of the β-glucosidase Cgl T from *Thermoanaerobacter brockii* and nucleic acids for producing the same. Said mutant variants show significantly increased thermostability and enzyme activity. Furthermore, the invention provides vectors, host cells and methods for producing said mutant variants of the β-glucosidase Cgl T. Also provided are artificial cellulosomes comprising the mutant variants of the β-glucosidase Cgl T and methods for the enzymatic hydrolysis of cellulosic biomass comprising said artificial cellulosomes and/or said mutant variants of the β-glucosidase Cgl T.

What does a patent look like?

- **Bibliographic information**
  - Inventor, proprietor, date of filing, technology class, etc.
- **Abstract**
  - Around 150 words as a search aid for other patent applications
- **Description**
  - Summary of prior art (i.e. the technology known to exist)
  - The problem that the invention is supposed to solve
  - An explanation and at least one way of carrying out the invention
- **Claims**
  - Define the scope of patent protection
- **Drawings**
  - Illustrate the claims and description
- **Others**
  - Sequence Listing, Indication for deposited biological material…

Structure of the description

- Title
- Field of the Invention
- Description of Prior art
  - *Teapot with one spout*
- Drawback of prior art
  - *Time-consuming*
- Problem to solve
  - *Reduce filling time*
- Solution
  - *Provide a second spout*
- Advantage of the invention
  - *The time needed to fill multiple cups is reduced*
- Definition of terms used
- Preferred embodiments (fall-back lines)
- Examples

Fig.1.

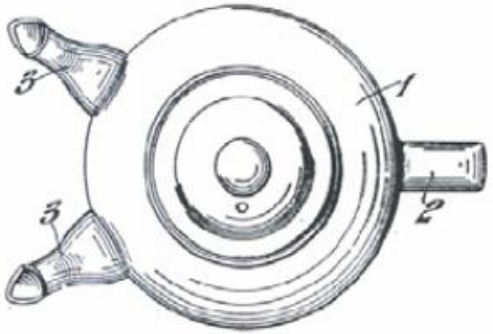


Fig.2.

Source: EPO Teaching Kit

Patents

Patent claims

Claims

Art. 69(1) EPC:

"The extent of the protection conferred by a European patent or a European patent application shall be **determined by the terms of the claims**. Nevertheless, the description and drawings shall be used to interpret the claims.

Art. 84 EPC:

"The claims shall define the matter for which protection is sought. They shall be

- **clear,**
- **concise** and
- **supported by the description."**

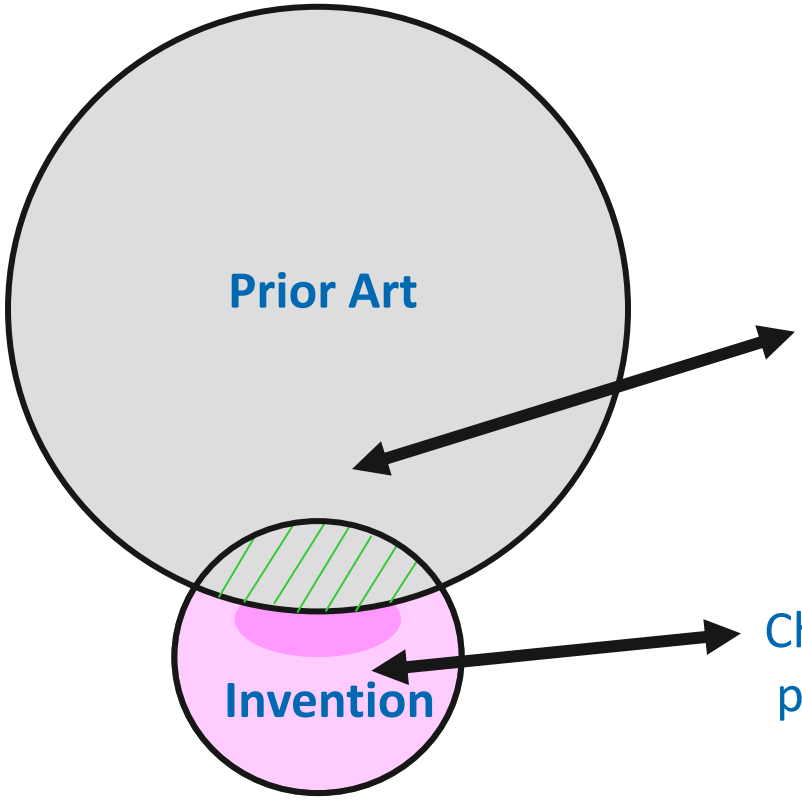
Claims

- The claims determine the scope of a patent.
  - In the claims the features are mentioned for which the patent holder claims the right of protection.
  - Combination of these features may not be used by a third party.
  - Otherwise: infringement of patent

- Independent claim(s) determine maximum scope of protection.

- An infringement exists if (and only if) the used product at least makes use of one independent claim.

Claims



Preamble

Characterizing part

Independent Claim

1. xxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxx
characterized in that
xxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxxxxx.

Claims

Example for one part claim

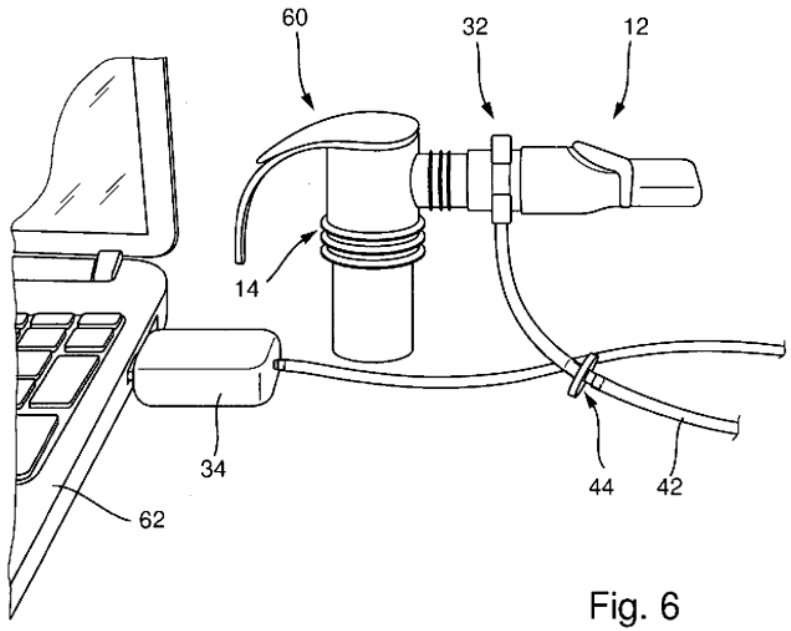


Fig. 6

Claims

Example for one part claim

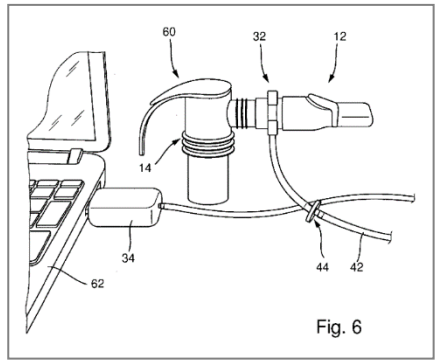


Fig. 6

1. **An inhalation support apparatus (30)** for an inhalation device (10) that has a mouthpiece (12) and an inhalation mixture generator (14) for supplying an inhalation mixture to be inhaled,

comprising

- a pressure sensor adapter (32), which can be arranged between the inhalation mixture generator (14) and the mouthpiece (12),

- and a control device (34) for controlling an entertainment program running on a data processing installation (62), wherein the control device (34) is configured to control the entertainment program as a function of the pressure changes.

Claims

Example for two-part claim

1. (original) A handpiece (100) for a medical or cosmetic processing device, having:
   - a connection line (102) at a connecting end (101);
   - a housing (104) in which a receptacle space is provided between a connecting end (101) and a processing end (103), a rotary drive unit for driving a rotary tool (210) that is attachable to the processing end (103) being able to be received in said receptacle space,

characterized in that

the handpiece (100) is able to be separated from the connecting end (101), wherein the handpiece (100) is designed such that the motor (110) upon decoupling of the housing (104) remains on the connecting end (101); and

the handpiece has a rotary clamping device (120) in which the rotary tool (210) is able to be attached.

Claims

- Features should suitably be formulated in a general manner
  - e.g. “fixing" instead of "screwing", "glueing, etc ...“, as this incl udes all types of fastening.

- Formulate features clear, avoiding relative terms
  - Avoid e.g .: "about", "approximately", "thin", "strong", “warm”, “cold”

- Use terms like
  - “such as”, “in particular", "preferably" only, if they do not cause confusion,
  - Better as alternative embodiments in a further dependent claim

Claims

- Note differences between “comprising" and "consisting of“.
- Claims must be supported by the description.
- Features / numerals are to be used consistently.
- Do not use brand names!

Examples

*A pharmaceutical composition **comprising** an inhibitor of dipeptidyl peptidase IV.*

*A pharmaceutical composition **consisting of** an inhibitor of dipeptidyl peptidase IV and glucose.*

Claims

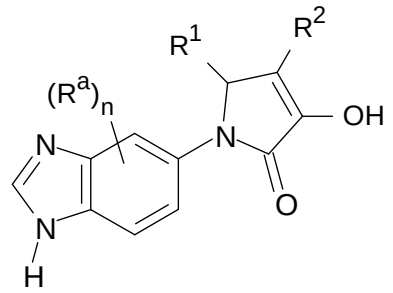
Basic Types of Claims - Categories

- Product (compound, material, fabric..)
- Apparatus/device
- Process (method for producing something, doing something …..);
  - Product obtained by the process is automatically protected with it!
- Use (of a product to obtain a specific result);
  - Use claim is a special type of process claims

Claims

Example: Process claim

26. **A process for preparation of a compound of formula (I)** according to any one of claims 1 to 15, which comprises preparing a compound of formula (I) from a compound of formula (II)



(II)

wherein R^a, n, R^1 and R^2 are as defined in claim 1.

Claims

Example: Method claim

1. **A method for detecting the presence of an optically detectable contamination, preferably blood or blood components, in a fluid stream in a substantially transparent hose line comprising the steps of:**

- directing a beam of electromagnetic radiation straight-lined across said optically transparent hose line and through said fluid stream from a first side of said substantially transparent hose line,
- locating an optical sensor on a second side of said substantially transparent hose line, wherein said optical sensor is located opposite to the means which emits the electromagnetic radiation,
- detecting the intensity of the electromagnetic radiation received by said optical sensor; and
- generating an alarm signal when said intensity of the electromagnetic radiation falls below a predetermined value,

wherein the influence of stray light is reduced by

- structural measures; and
- means of signal modulation and software evaluation.

Claims

Example: Product claim

1. **A sensor system for detecting the presence of blood or blood components in a fluid stream in a substantially transparent hose line (6)** comprising a means for emitting electromagnetic radiation (1), an optical sensor (2), a housing (5) and means for reducing the influence of stray light (3, 4), wherein the optical sensor (2) is located opposite to the means for emitting electromagnetic radiation (1), the hose line (6) is located between the optical sensor (2) and the means for emitting electromagnetic radiation (1); and wherein the electromagnetic radiation is transmitted straight-lined from the means for emitting electromagnetic radiation (1) through the fluid stream in the substantially transparent hose line (6) to the optical sensor (2).

Patents in Life Sciences

Claims

Example: Product claims

Nucleic acid molecule comprising the nucleotide sequence of SEQ ID No. 1.

Vector containing a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No.3.

Host cell transformed with a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No.4.

Pharmaceutical composition comprising a Protein/Polypeptide comprising the amino acid sequence of SEQ ID No. 5.

Claims

Example: Use claims in biotech patents

EPO

1. Substance X for use in the treatment or prevention of disease Y.

(Purpose-related product claim, for all EP applications as from 29.01.2011)

US PTO

1. A method of treating disease Y, comprising administering to a subject in need thereof a composition comprising compound X , or a pharmaceutically acceptable salt thereof.

Rest of the world

1. Use of substance X for the manufacture of a medicament for treating or preventing disease Y.

(so called „Swiss-type claim“, use claim, in EP possible until 28.01.2011)

Claims

Example: Diagnostic methods

1. A method for screening patients with a cancer comprising i) determining in a tumor sample **obtained from a patient** an expression level ELA_i-ELA_n of one or several genes GA_i-GA_n representative of human adaptive immune response and an expression level ELI_i-ELI_n of one or several genes GI_i-GI_n representative of human immunosuppressive response,
ii) comparing the expression levels ELA_i-ELA_n and ELI_i-ELI_n determined at step i) with predetermined reference values $ELRA_i$-$ELRA_n$ and $ELRI_i$-$ELRI_n$ selected such as said predetermined reference values separate a panel of patients with a cancer into two groupings according to the expression level of said genes and to survival of patients according to Kaplan Meier curves analyses and associated logrank p values
iii) concluding whether the patient has a good or a bad adaptive immune response and a good or a bad immunosuppressive response,
wherein a good adaptive immune response or a good immunosuppressive response is one in which….

Claims

Example: Screening methods

1. **A method of screening a compound for its ability to modulate the activity of a Grueneberg Ganglion (GG) neuron**, the method comprising

    a) administering a compound to a particulate guanylyl cyclase A receptor (pGC-A), a particulate guanylyl cyclase G receptor (pGC-G) or both, and

    b) determining the activity of the pGC-A, the pGC-G or both in response to the compound,

wherein the determined activity in response to the compound indicates that the compound can potentially modulate the activity of the GG.

Claims

Example: Screening methods

Problem with claims like:

2. A compound obtained/identified/produced by use of the screening method/process according to claim 1.

- So-called “Reach-through claims” **are not patentable.**
- Compound defined by function only, not by structure;
- Any compound having this function would fall under the claimed scope;
- Undue burden for the person skilled in the art to identify any compound having this function or activity;
- Skilled person cannot re-work the invention based on the description (insufficient disclosure);
- Skilled person must make new inventions.

Claims

Examples: Microbiological process

1. A process for microbial production of xylitol from xylose containing biomass comprising:

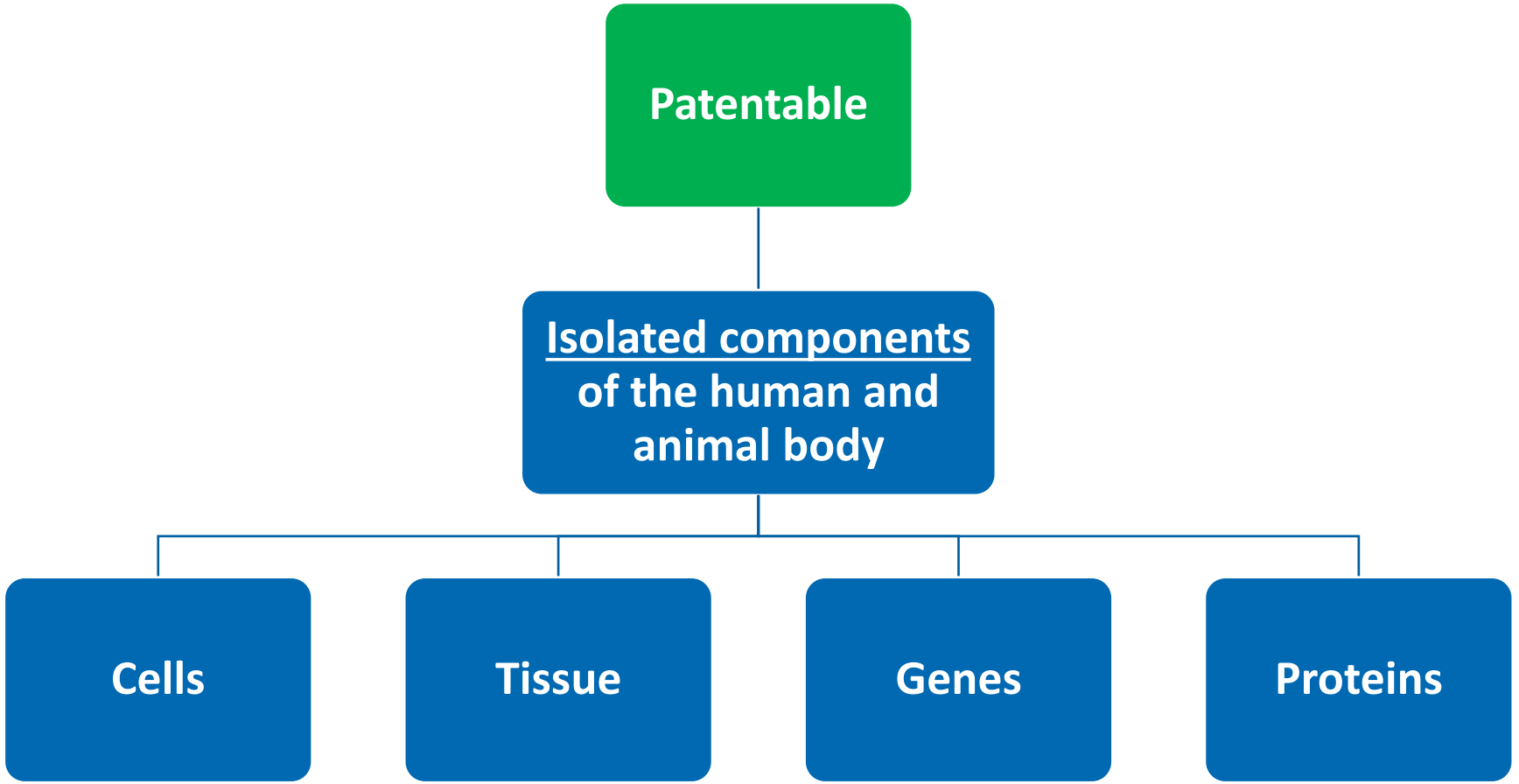
a) growing of yeast strain in a solid medium;

b) inoculating the yeast strain obtained from step (a) in a seed medium containing seed fermentor;

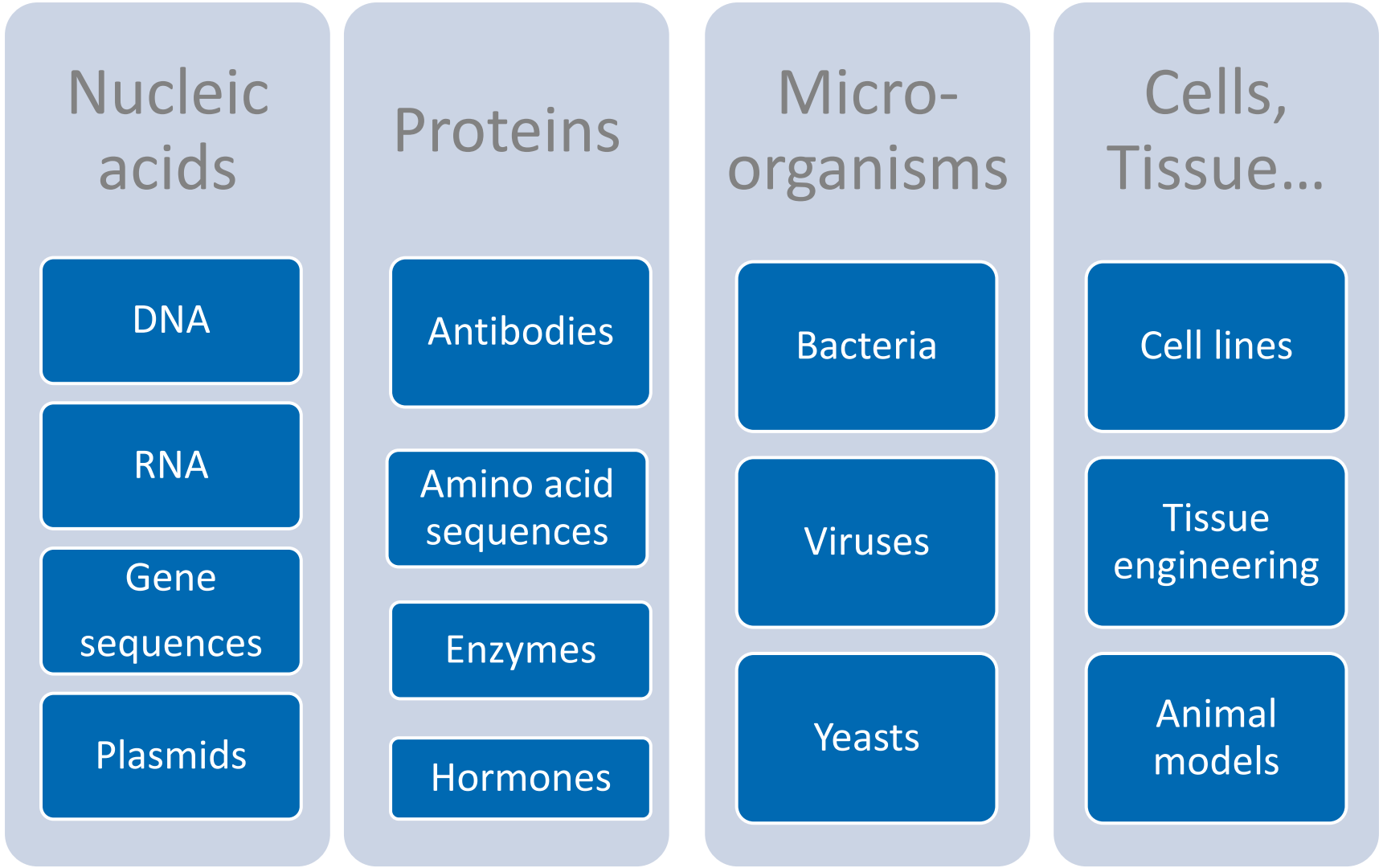
c) culturing the yeast strain from step (b) by transferring in production fermentor having xylose containing production medium; wherein fermentation of said xylose containing biomass is carried out with yeast strain capable of converting xylose to xylitol; and

d) removing the yeast strain from said production medium and recycling it for continuous production of xylitol.

Not Excluded from Patentability



Patentable Biological Material in Europe



Law Change in the U.S.

Supreme Court's *Myriad* decision and the PTO Patent Examination Guidance on Eligibility of Claims to Products and Processes Derived from *Natural Sources* (2013)

- Gene patents owned or controlled by Myriad Genetics were challenged in the United States, in particular certain claims in issued patents that cover
  - isolated DNA sequences,
  - methods to diagnose propensity to cancer by looking for mutated DNA sequences, and
  - methods to identify drugs using isolated DNA sequences.

- Supreme Court invalidated Myriad's claims to isolated genes. The Court held that merely isolating genes that are found in nature does not make them patentable.

Law Change in the U.S.

New Guidance of USPTO to patent examiners released on March 4, 2014:

- Myriad decision is extended **beyond nucleic acids** also to *"chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials, (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other* ***substances found in or derived from nature****."*
- regardless of whether limitations such as "isolated," "recombinant," or "synthetic" are part of the claim
- Extends to methods of diagnosis!

Other Countries

- China: Diagnostic methods and methods of treatment not patentable
- India: No patents for biotech inventions at all!
- Australia: Recent decision of High Court (also Myriad):
  - Nucleic acid sequences are not patentable at all, indepedently whether they are artificial or isolated from nature
  - Proteins / amino acid sequences remain patentable

Value of assets may differ from country to country!

Biotech Inventions in Germany

Patent protection for:

- Biological material isolated from its natural environment or produced by means of a technical process.

- Isolated elements of the human body including the sequence or partial sequence of a gene, **however**: use for a specific function must be indicated in claim (**No** absolute product protection!).

Biotech Inventions in Europe

Patent protection for:

- A DNA sequence when a function thereof is indicated in the description (no indication in the claims necessary - different from Germany) **Absolute product protection!**

- 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.

Europe vs. Germany

Granted European Patents covering genes per se cannot be revoked in Germany solely for that reason

However, the scope of protection of a corresponding European Patent as interpreted by German Infringement Courts cannot be predicted.

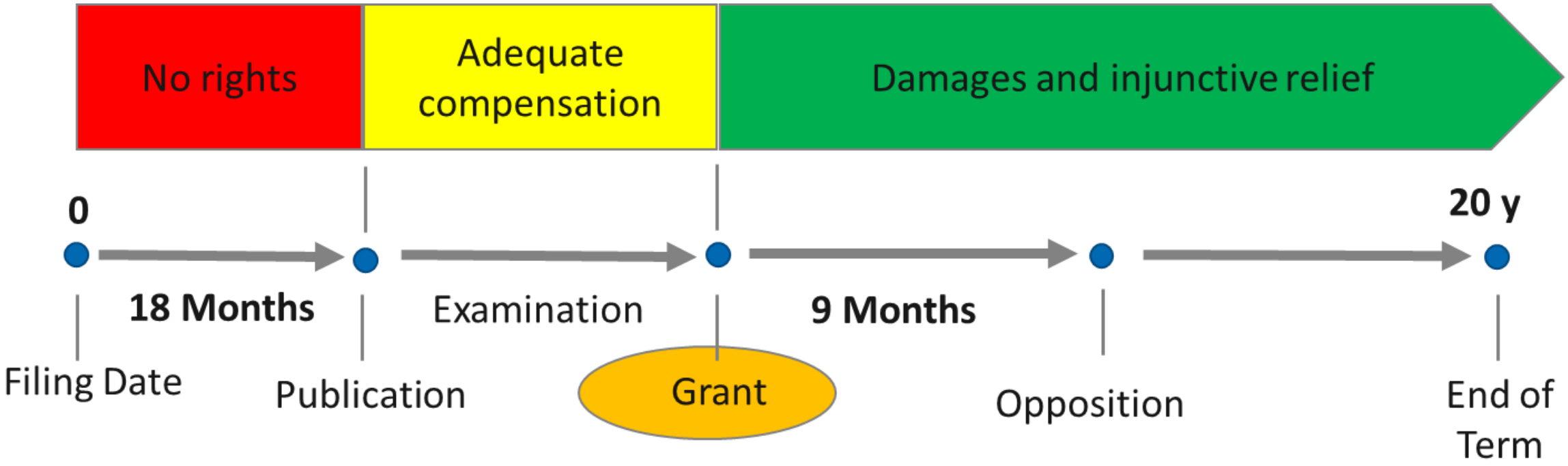
Europe vs. Germany

Consequence:

File Biotech-Applications in Europe!

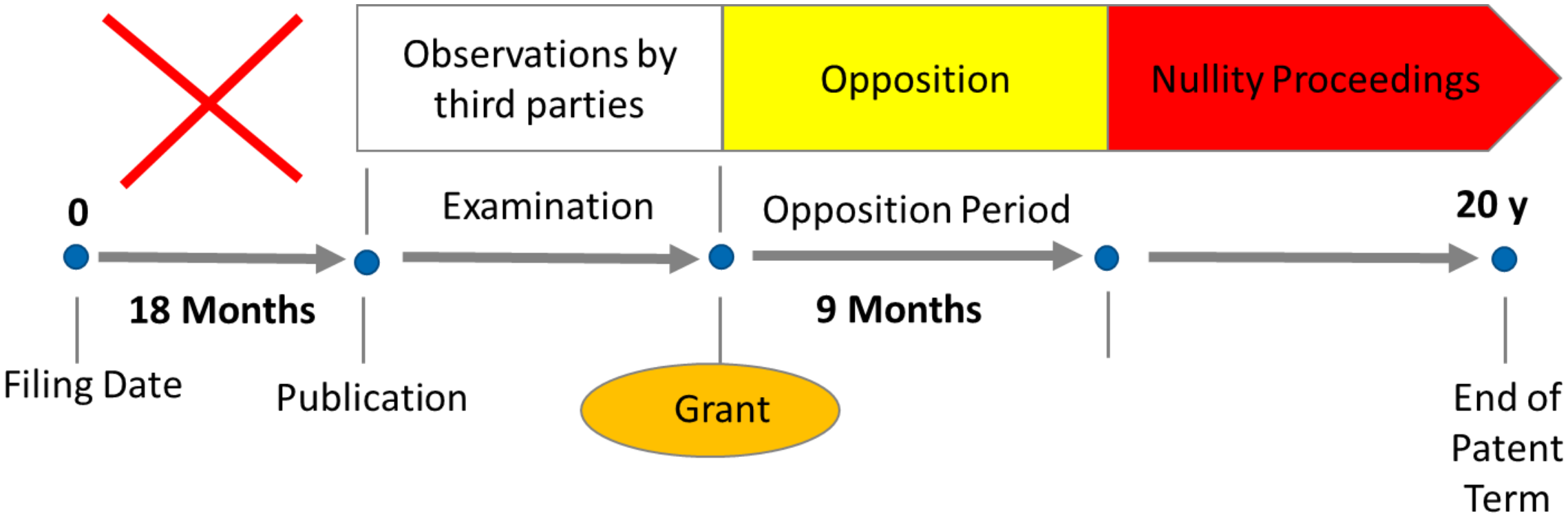
Attacking and defending patents

Rights of the Patentee



- Prerequisite for damages and injunctive relief claims: **granted patent which is in force**

Attacking Patents



What of?

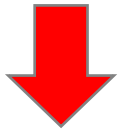
Patent infringement

- Does my invention fall in the protection scope of another patent, to which I have no rights?

Freedom-to-operate (Non-infringement) vs. Patentability

- Patent allows the owner / licensee to prohibit third parties from using the invention
- Patent is no permission for the patentee to use its own patented invention

Use of an invention which is patented from a third party



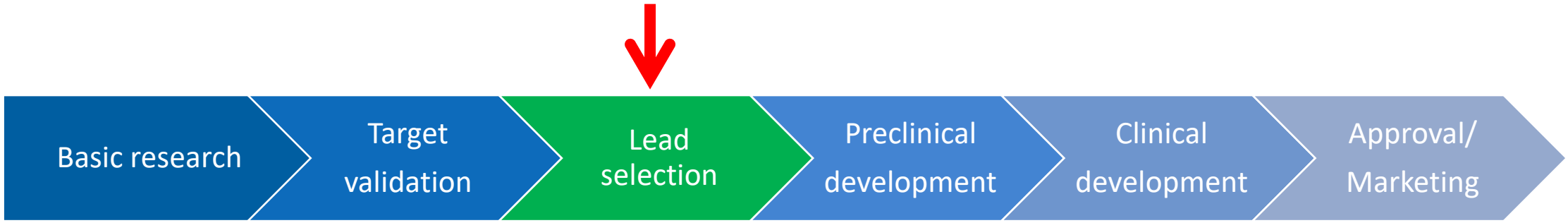
Patent infringement

What of?

Time point of FTO-searches

Goal: early identification of “disturbing“ rights of third parties

Practise example: Pharmaceutical value chain



- In early stages of product development
- Before enduring high costs
- Periodically (e.g. repeat every 6 month)

Where do I find patent information?

Search strategies

1. Novelty Search, Prior Art Search
    - Patent databases, Don‘t forget scientific literature!

2. Check legal status (important for FTO!)
    - Search in national patent registers

1. Novelty Searches

DEPATISNET

- Search for patents and patent applications worldwide;
- Patentfamilies can be searched;
- Full text documents, can be searched;
- „bulk-download“ of multiple IP rights as ZIP-file;

1. Novelty Searches

ESPACENET

- Search for patents and patent applications worldwide
- Full texts divided in claims and description
- CCD Tool (Citations)
- No „bulk download“ of fulltect documents, only of cover pages
- Advantage: Patent-Translate – Tool.

1. Novelty Searches

PATENTSCOPE

- Search-Tool of WIPO;
- Search for patents and patent applications worldwide;
- Good for search of international (PCT, WO) applications;
- Full text documents, can be searched;
- File registry – legal status information;
- Multiple translation tools (google translate, WIPO translate etc..

1. Novelty Searches

Google Patents - Be careful!

- Full texts are provided directly;
- Citations shown;
- Links to other databases and patent registers;
- Advantage: translation tool, good for asian languages, especially Chinese;
- Search for prior art possible;
- Google Scholar – search for scientific literature possible.

2. Legal status searches

EPO REGISTER

- Legal status;
- Divisional applications?
- Published documents;
- File inspection;
- Links to national patent offices of EPO member states.

2. Legal status searches

DPMA REGISTER

- Legal status;
- Published documents;
- File inspection.

2. Legal status searches

US PTO PATENT CENTER

- Legal status;
- Divisional applications?
- File inspection;
- Patent Term Adjustments!!!

National patent registers of other countries, as far as available

Other Databases (commercial)

SciFinder:	Search for chemical structures (CAS)
MarPat:	Search for chemical Markush structures
DERWENT:	Anything
THOMSON INNOVATION:	with graphical evaluation tools
INVENTION NAVIGATOR:	with graphical evaluation tools,
	good download function of search result reports
PATBASE:	Same functions as INVENTION NAVIGATOR

Patent Strategy for Startups

Goal

Obtaining property rights with expected economic benefits

- Own utilization/use
- Licensing
- Blocking of competitors - blocking patents
- Do not base your decision to protect solely on technical arguments
- Non-exploited and non-exploitable property rights tie up capacities, resources and money!

Where?

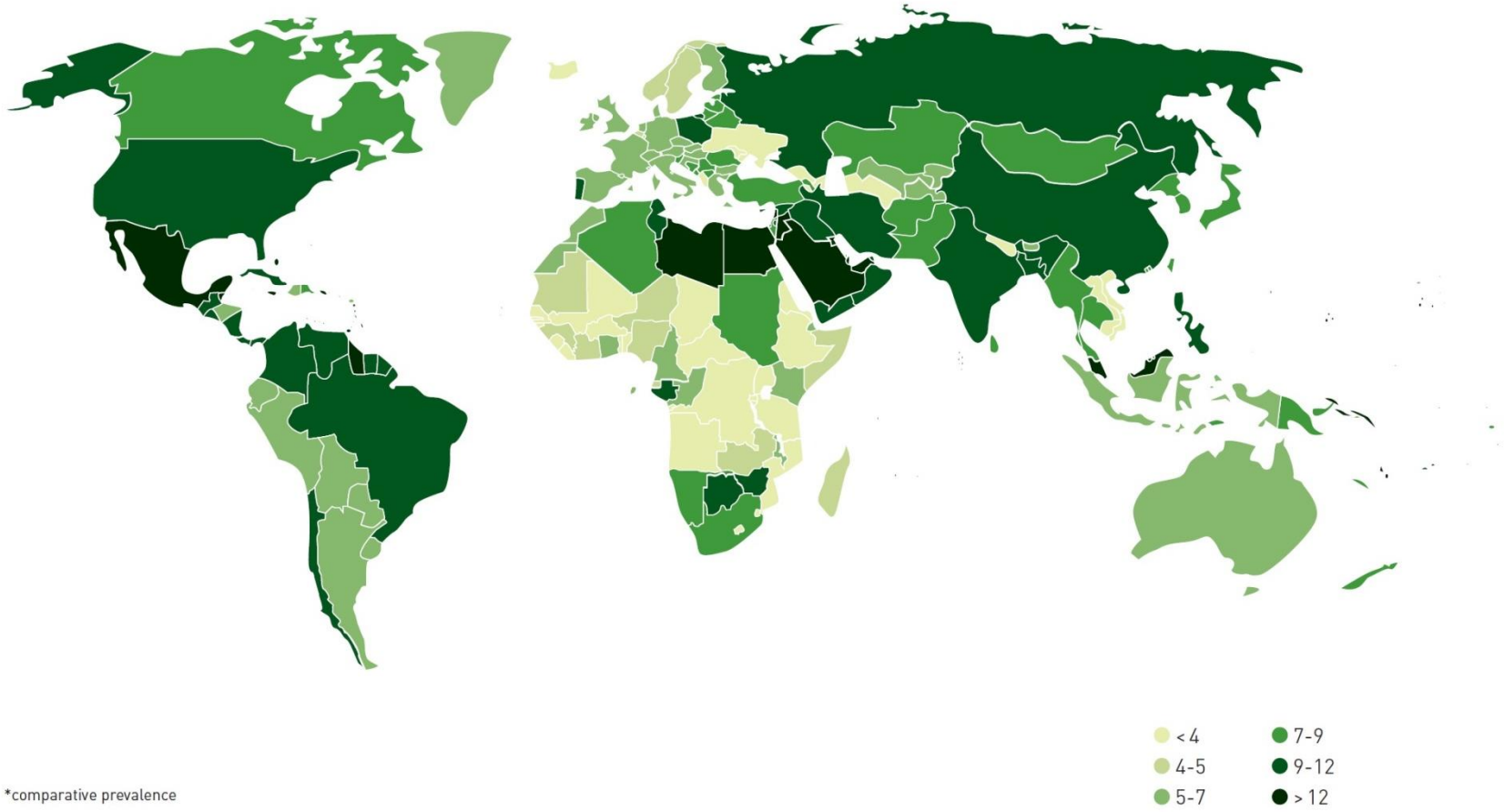
Where should I register/file my IP rights?

- Home market
- Important international sales markets
- Own production sites
- Production sites of the competition

Where?

Practical example: Development of a new antidiabetic drug

Incidence of diabetes (%), 2011

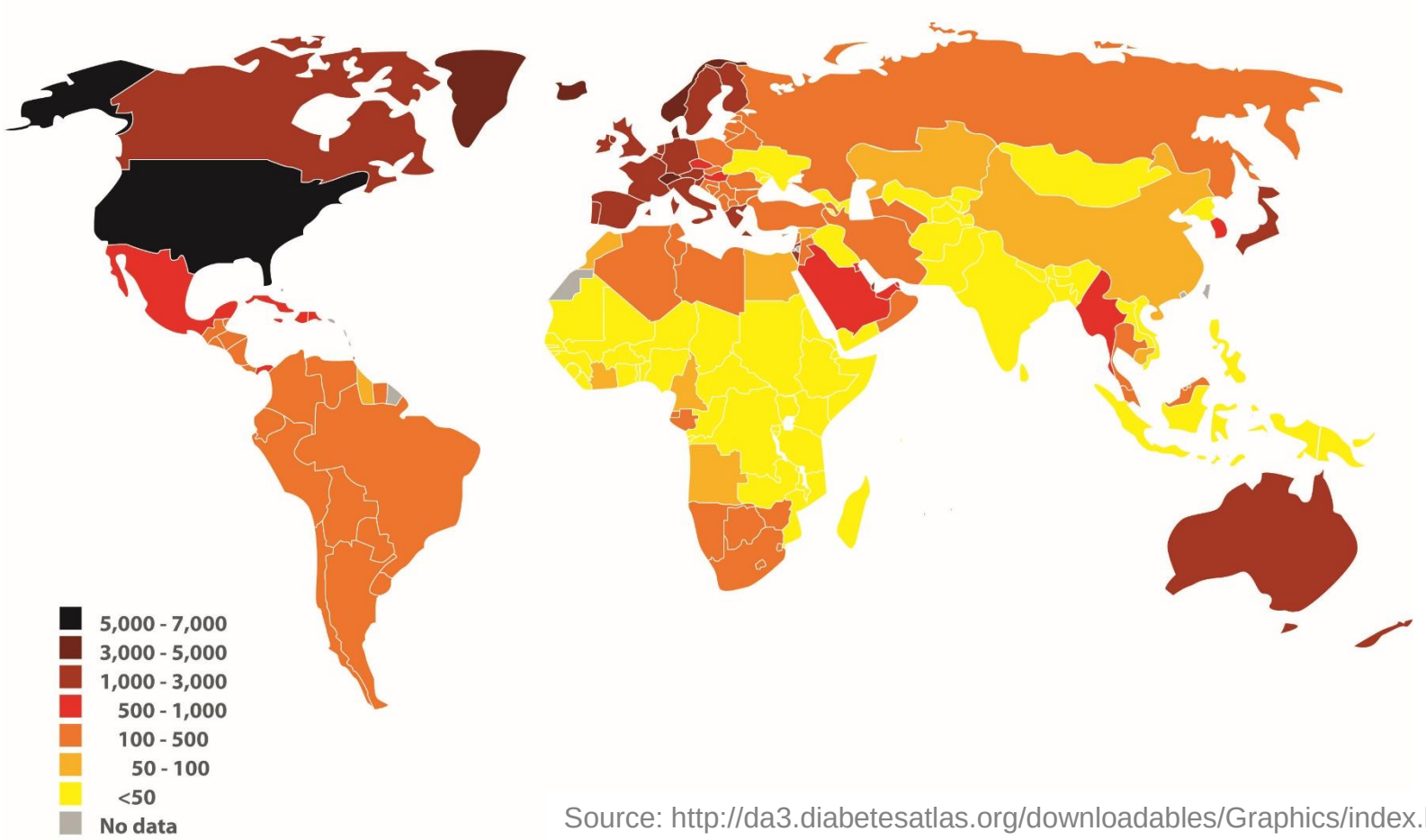


Source: http://www.idf.org/diabetesatlas/5e/diabetes

Where?

Practical example: Development of a new antidiabetic drug

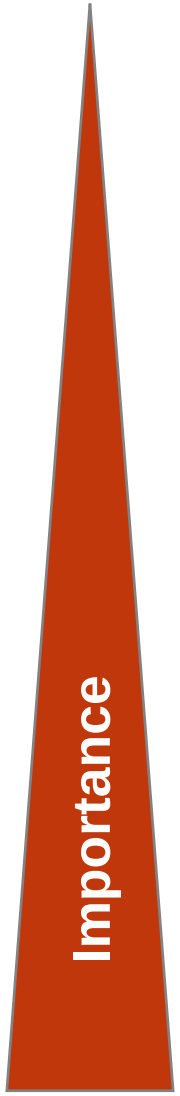
Average expenditure on antidiabetes drugs per person (US dollars), 2007



Source: http://da3.diabetesatlas.org/downloadables/Graphics/index.html

Where?

Number of countries vs. costs

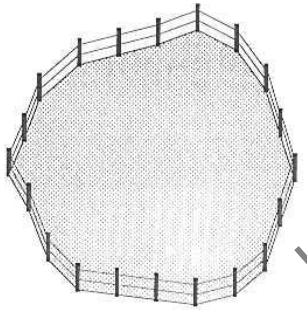


1. Portfolio/blocking patents
   - Europe, USA and Japan (China?)
   - Approx. 10,000-15,000 €
2. Supporting inventions (detection methods, tools, etc. that serve the main invention)
   - Countries where you can register in English:
   - Australia, Canada, USA, Europe, Hong Kong, India, Israel, New Zealand, Singapore, South Africa
   - Approx. 20,000 to 25,000 €

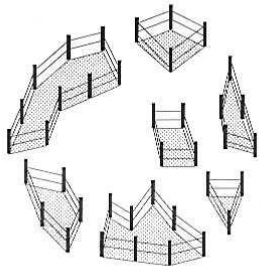
3. patents for important products and processes
   - No. 2 + Brazil, Eurasia, China, Japan, Korea, Mexico
   - Approx. 60,000-85,000 €

4. Patents for crown jewels
   - No. 2 + No. 3 + Algeria, Chile, Colombia, Costa Rica, Dominican Republic, Egypt, Indonesia, Malaysia, Morocco, Nigeria, Peru, Philippines, Thailand, Trinidad & Tobago, Ukraine, Vietnam
   - Approx. 125,000-175,000 €

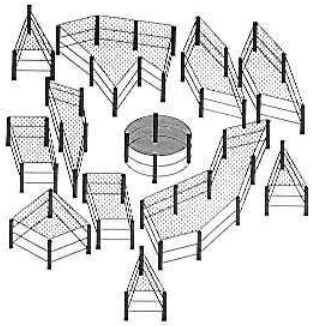
Development of a patent portfolio



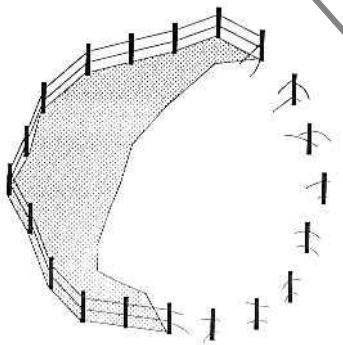
Single patent,
Wide protection area



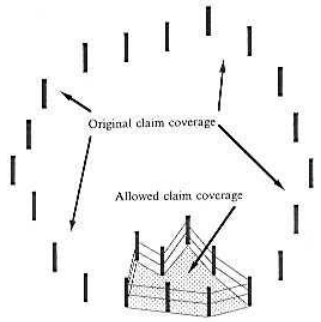
Several patents with a narrower scope of protection



Blocking strategy,
Patent flood



Protection area too wide,
restricted after objection...



... or already in the examination process

Patent portfolio – An Example

Medical use of a new class of active substances,
Clinical research and development

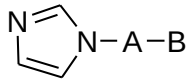
Year 1: Basic registration, broad protection of the medical concept

[1] A pharmaceutical composition for parenteral, enteral or oral administration comprising at least one inhibitor of dipeptidyl peptidase IV or a pharmaceutically acceptable salt thereof.
[3] Use of a pharmaceutical composition according to claim 1 for the manufacture of a medicament for the prevention or treatment of a disease selected from Alzheimer's disease and Down's syndrome.

Patent portfolio – An Example

Years 1-8: Numerous patent applications for specific chemical substance classes

1. Verbindung der Formel 1, einschließlich pharmazeutisch akzeptabler Salze derselben, umfassend alle Stereoisomere und Polymorphe:



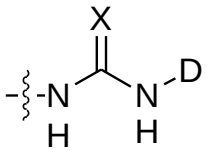
Formel 1

wobei:

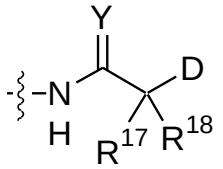
A eine unverzweigte C_3 Alkylkette ist;

und

B eine Gruppe ist, ausgewählt aus (VI) oder (VII):



(VI)



(VII)

wobei:

wenn B eine Gruppe (VI) ist, D Dihydrobenzodioxin, Benzodioxol, Benzodithiol, …

Patent portfolio – An Example

Years 3 to ...: Numerous patent applications for tools

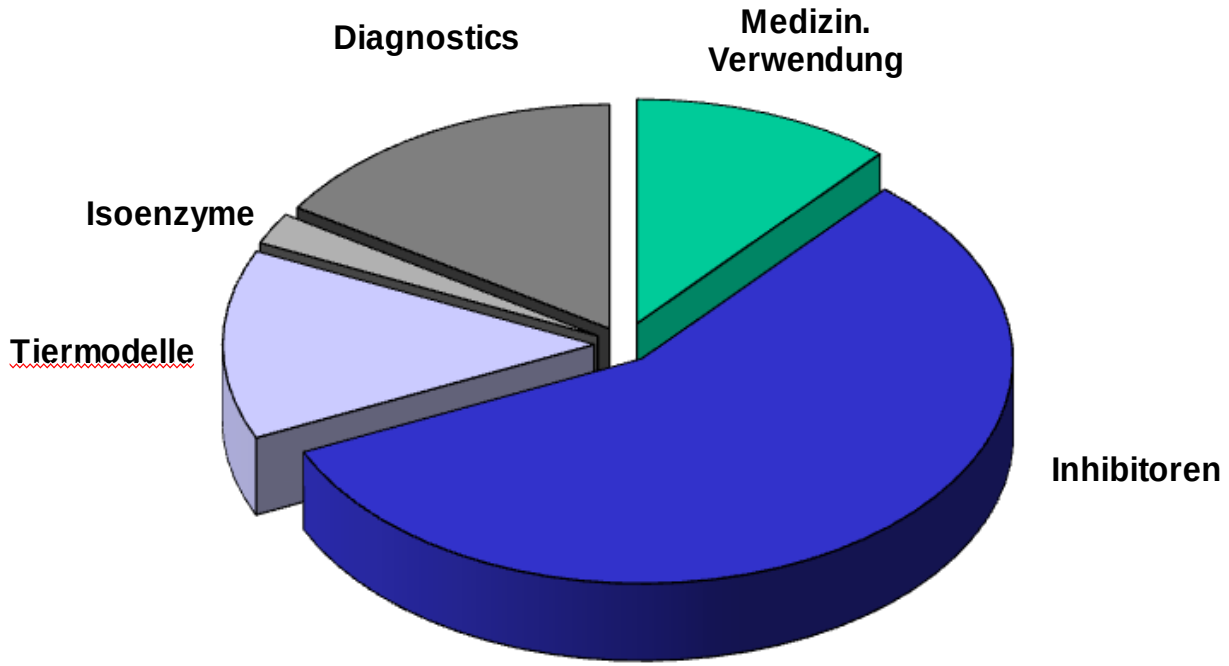
- Animal models
- Analytical methods, assays
- Antibodies
- Isoenzyme

1. A transgenic non-human animal overexpressing dipeptidyl peptidase IV, comprising cells containing a transgenic DNA encoding dipeptidyl peptidase IV.

1. Antibody that selectively binds to the pyroglutamate-bearing amino-terminus of MCP-1 (MCP-1N1pE), where selective binding means that it does not cross-react with epitopes outside the pyroglutamate-bearing amino-terminus of MCP-1 N1pE.

Patent portfolio – An Example

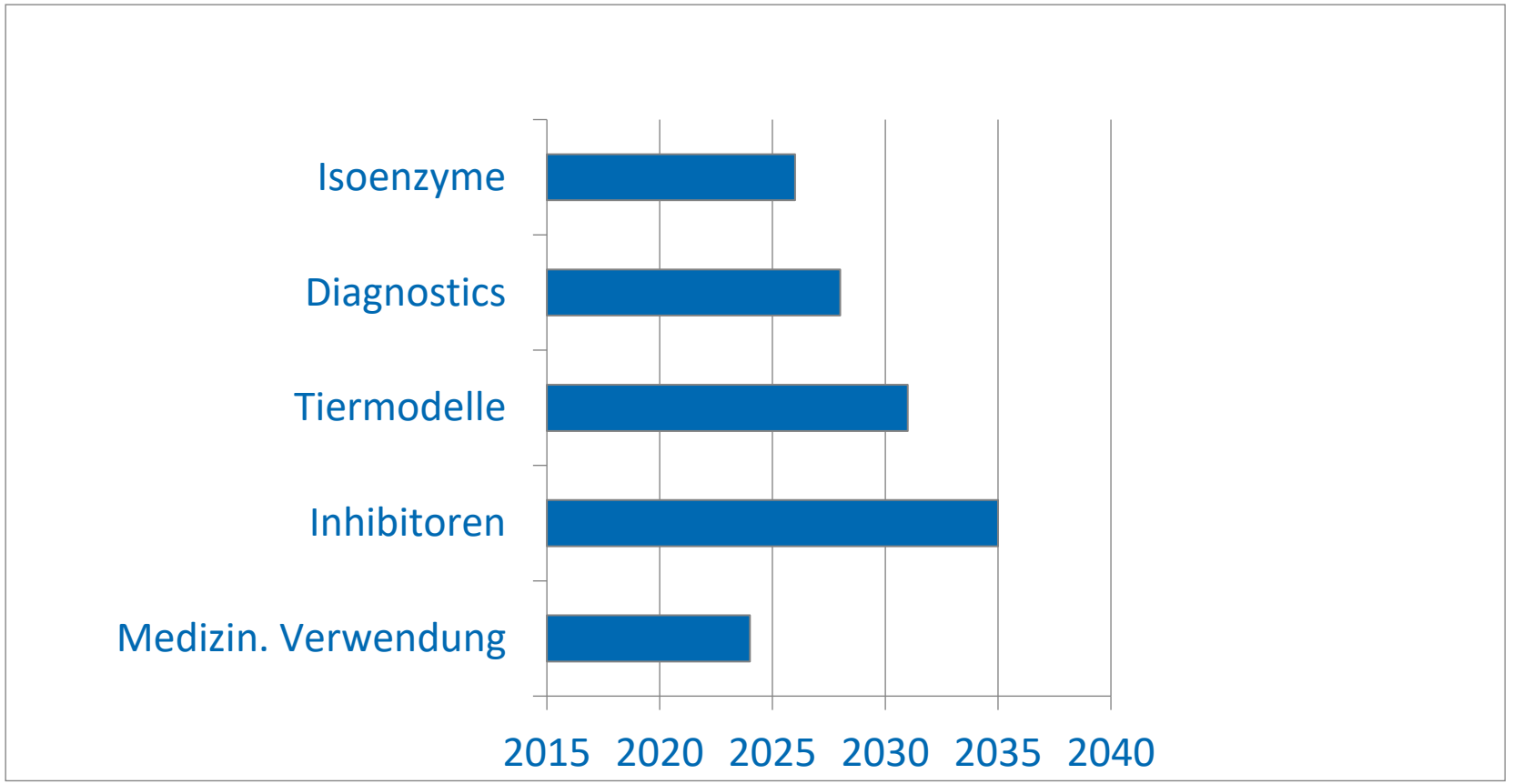
44 patent families, > 650 patent applications worldwide



Medicine. Administration	Inhibitors	Animal models	Diagnostics	Isoenzymes
5	25	6	7	1

Patent portfolio – An Example

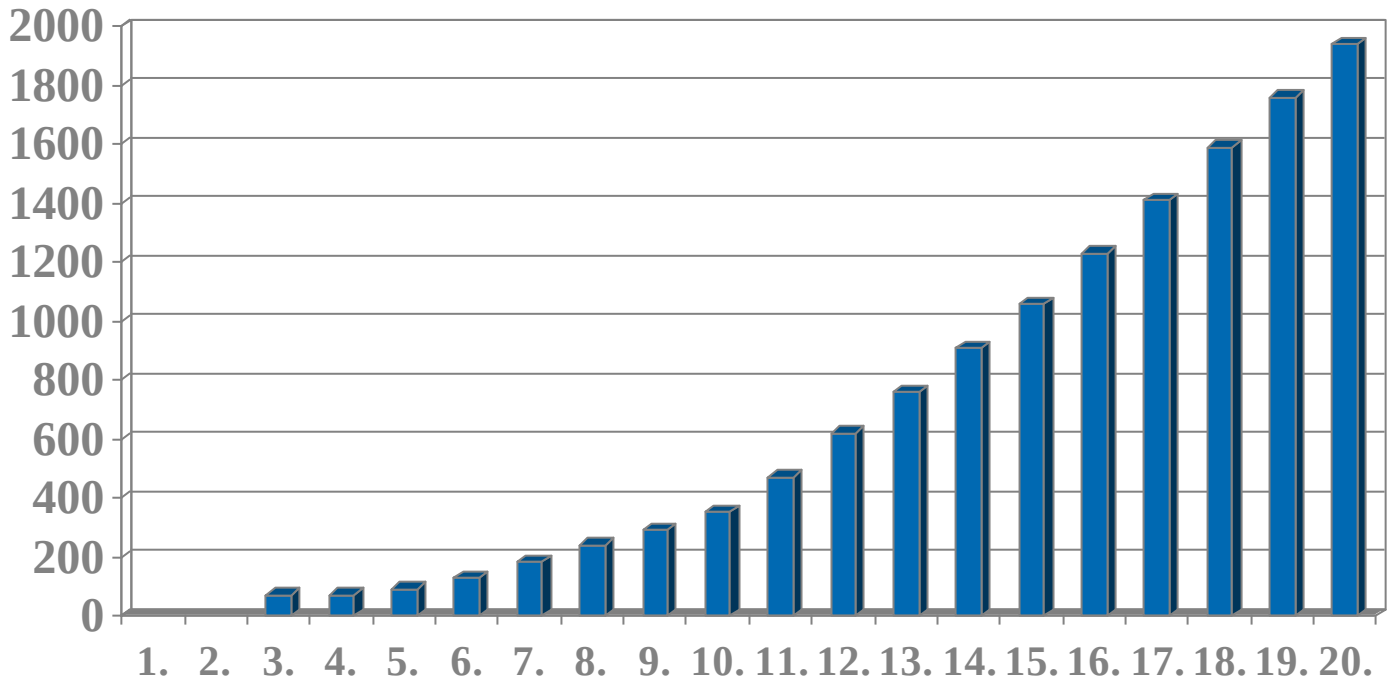
Patent terms



Patent portfolio – Maintenance

- Pay annual fees to maintain the patents from the 3rd to the 20th year
- Conduct regular portfolio review meetings
  - Giving up property rights that are no longer needed costs money and resources
  - Patent no longer protects a product
  - Patent is no longer needed to block a competitor
- Conduct regular review meetings to complete and expand the patent portfolio
- Competitor monitoring / FTO

Renewal fees for German patents/patent applications



Strategies for patent term extension

Problem particularly for products with very long development times, approval procedures and/or long product lifetimes

Example pharmaceutical industry
Statutory: supplementary protection certificates, up to an additional 5 years
Strategies for extending the monopoly position

"chiral switch": conversion of a racemic drug substance into a single enantiomer or into a pure form

New galenic forms

Selection invention: a single molecule that belongs to a larger family of substances.

New use: 1st and 2nd (non)medical indication

Combinations of active ingredients

IP CANVAS

IP CANVAS for a Startup

Analyzing the IP Situation:

- Your IP Rights
- Freedom-to-Operate
- Third Party IP Rigths
- Strategy (Future)
- Finance

IP CANVAS for a Startup

YOUR IP RIGHTS

- What special or unique elements, know-how etc. do you have?
- E.g. Special brand; patent; cutting edge technology; know-how; etc.
- Do you already own IP rights? If so, which?
- Do your competitors protect their IP rights? If so, how?
- Which IP rights are crucial for you and which are nice-to-haves?

IP CANVAS for a Startup

FREEDOM TO OPERATE

- Do you depend on know-how or products of third parties (licenses, contracts, etc)?
- Which countries do need your IP rights to be protected in?
- Which IP rights do you need in order to guarantee full operability?

IP CANVAS for a Startup

THIRD PARTY IP RIGHTS

- Might you infringe the IP rights of third parties through your activities? (Brands, trademarks, patents, copyright, etc).
- If so, what action could you take?
- Might third parties infringe your IP rights now or in future?
- If so what action could you take? Do you need a monitoring service?
- Do you have the resources (time, people, know-how)?

IP CANVAS for a Startup

STRATEGY (FUTURE)

- What are the future possible developments in your core market? E.g. related to technology, marketing, competitors, distribution, products.
- In which areas should you focus our attention to in order to remain competitive?
- What are the consequences for IP?

IP CANVAS for a Startup

FINANCE

- Revenues: are your IP rights crucial to securing and growing your revenue streams? If so, how?
- Could you license our IP rights (patents, designs, etc) to third parties? If so, to whom and is it advisable (given competition)?
- Costs: How many trademarks/designs/patents do you have to file protection for?
- What are the costs related to filing and keeping up your IP rights? (one-time as well as recurring).
- What would be your annual IP budget?

IP CANVAS for a Startup

NEXT STEPS

- Which IP Rights should you secure first?
- How long will it take and what are the crucial deadlines (e.g. patent filing dates)?
- Do you need to set-up periodic meetings to review our strategy?
- If so, how frequently?
- What are the next steps and who is responsible for each of them?

Individual Sessions

Dr. Jörg Smolinski

Kailuweit & Uhlemann
Patentanwälte Partnerschaft mbB
Bamberger Str. 49
01187 Dresden

Tel.: +49 (0) 351 470 37 -0
E-Mail: info@ku-patent.de
URL: www.ku-patent.de

Matthias Hoffmann

MAIKOWSKI & NINNEMANN
Patentanwälte Partnerschaft mbB
Kleine Fleischergasse 2
04109 Leipzig

Tel.: +49 (0) 341-30 868 300
E-Mail: hoffmann@maikowski-ninnemann.com
URL: www.maikowski-ninnemann.com

Thank you very much for your attention!