

SPARK Europe Webinar Series 2022

How to deal with inventions and what Technology Transfer has to do with your day-to-day business - Patents, Inventions and Innovations

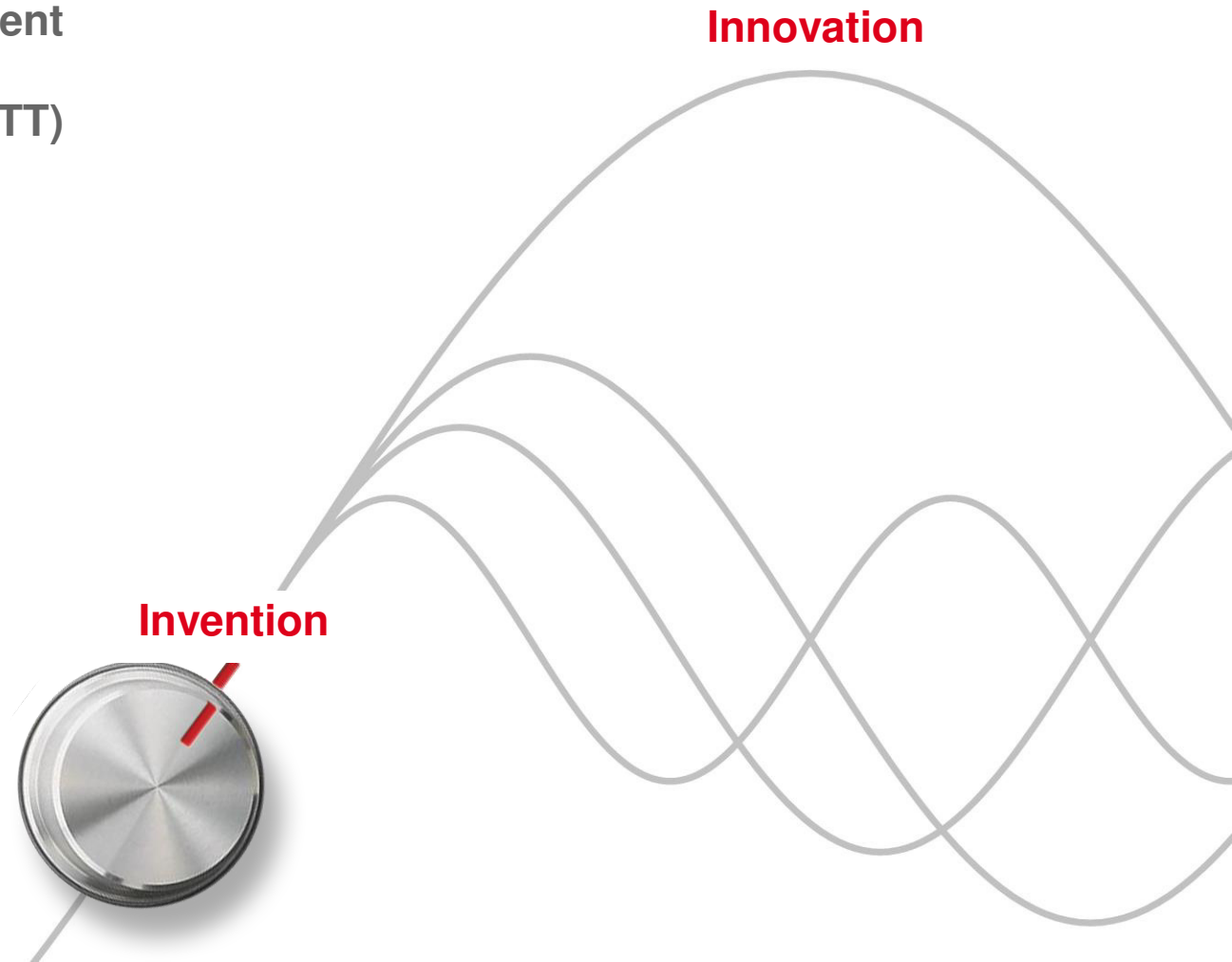
Dr. Sabina Heim, Ascenion GmbH

What is IP?

From invention to patent

Technology transfer (TT)

Patent exploitation



What is IP?

- Intellectual property (IP)
 - legal concept: exclusive rights are recognized for creations of the mind
- IP law
 - grants owners exclusive rights for their IP, e.g. musical, literary, and artistic works, and inventions, and designs.
- types of IP rights
 - Copyright
 - Trademarks
 - Patents
 - industrial design rights
 - trade secrets (in some jurisdictions)
- most important IP rights in TT
 - patents and trademarks
 - copyrights



The IP Problem

- Interest of the inventor >>> maintain invention secret as technical advantage
- Interest of the public >>>> Improve technology available for the public
- **Solution:**
 - Provide time-limited exclusivity for inventor in exchange for disclosure to the public >>>> **Patent**

Trade Secrets

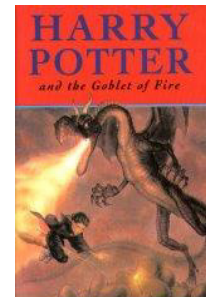
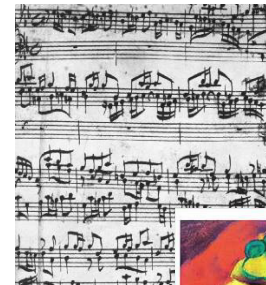
- Inventions can be kept secret by non-disclosing their subject.
 - Only reasonable, if the invention can be exploited nevertheless
 - typically a service or the product of a secret production process
- Problems :
 - disclosure (somebody natters...)
 - analysis of the product by a third party
 - a third party files a patent, which covers my invention
(but in Germany: right of prior use “Vorbenutzungsrecht”)



Copyrights

Protection of intellectual creations

- strong protection conferred by the copyright law
- protection against copying, performance and changing, without the prior written consent of the author
- Protection is granted for
 - books
 - music
 - pictures
 - scientific publications
 - computer programs



What kind of rights for which technology?

- Technical protective rights
 - Patents
 - utility models "Gebrauchsmuster"
 - Variety protection

- Non-Technical protective rights
 - Trademarks
 - Designs ("Geschmacksmuster")
 - Copyright





What is IP?



From invention to patent



Technology transfer (TT)

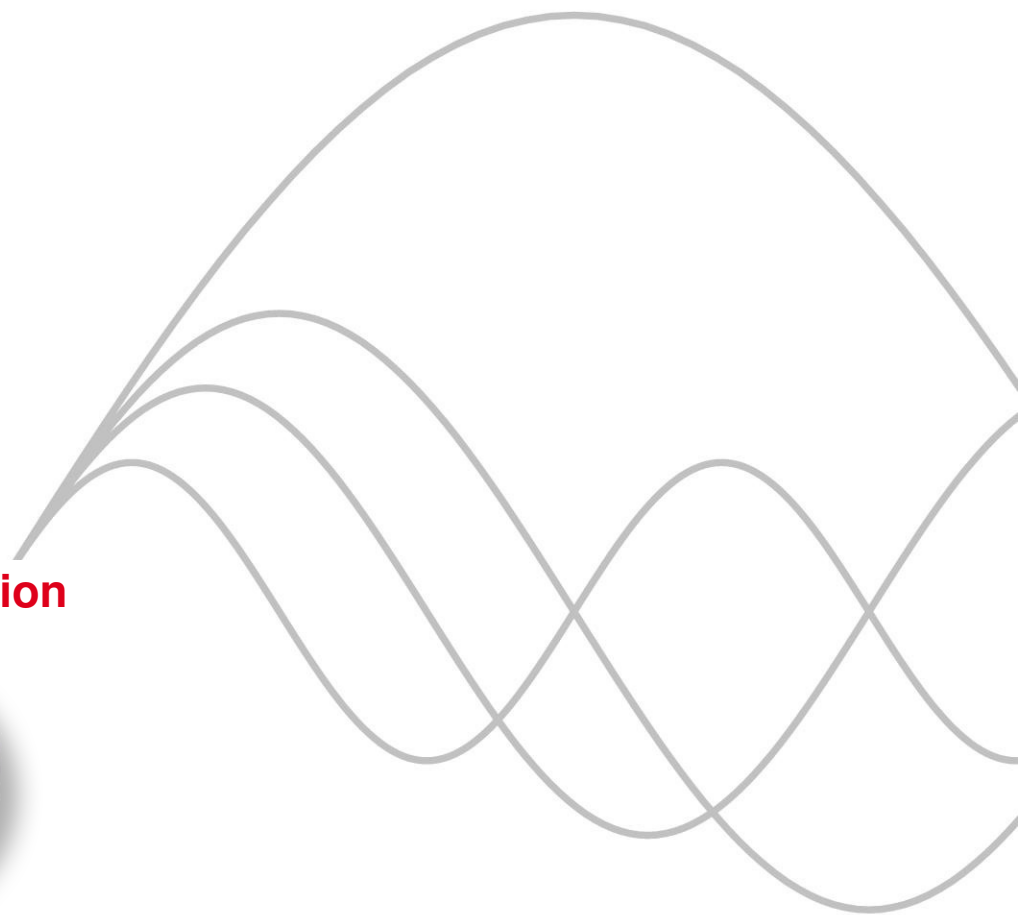


Patent exploitation



Invention

Innovation



Novel idea - maybe an invention?

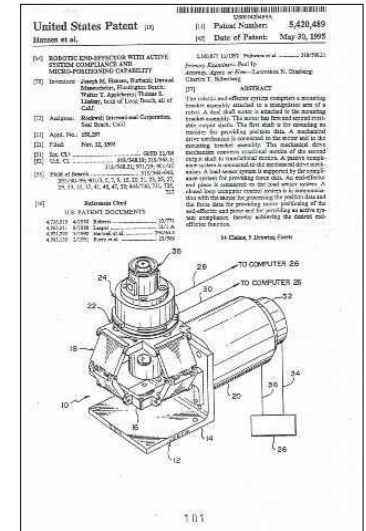
Novel idea / data / method / material?

- Check state of the art, as also performed in the discussion of a paper
 - Is the idea novel?
 - Are your results surprising and not obvious?
 - Could the idea/data be used commercially?
- Which kind of invention is addressed?
- third parties involved (ownership)?
- invention disclosure should be filed

Shall a patent be filed?

Both technical and economic requirements should be fulfilled:

- Patentable
 - chance, to get a patent granted
- Patent-worthy
 - market potential – is it justifiable to file a patent application, due to commercial exploitation potential?



50 euro-uv repro by H. Grobe

Is the invention patentable?

Requirements

Novelty

- absolute novelty is required!
- before the day of filing a patent application, the invention must not be disclosed, neither by written or oral communication, nor public use of the invention. Neither **by the inventor**, nor by anybody else.

Inventive Step

- beyond the state of the art
- not obvious
- the solution was not expected as part of standard further development. The results are surprising.

Commercial Applicability

- Possibilities to use, apply and market the claimed



State of the art search – novelty and inventive step

General sources

- Publication databases (e.g. www.ncbi.nlm.nih.gov/PubMed/)
- Google – universal source: technologies, competition, similar products

Free IP-Databases

- Espacenet
 - Search for international patent families (www.espacenet.com)
- EPOLINE:
 - Status of applications in EP (online file inspection www.epoline.org)
- WIPO/Patent Scope
 - Search International and National Patent Collections www.wipo.int/patentscope/en/
- Google Patents
 - Search in most relevant databases of national patent offices <https://patents.google.com/>
- National patent offices, e.g. USPTO, DPMA (DEPATISNET) etc.:

Commercial Tools

- Derwent, minesoft PatBase, PatSnap etc.

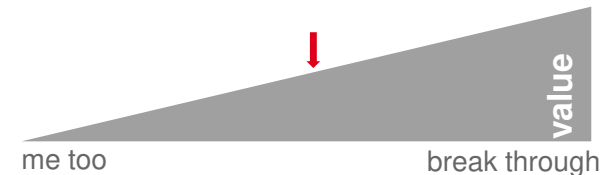
Patentworthiness

Aspects besides patentability: patentworthiness including market potential

- Achievable scope of protection of a potential patent
- Dependence on other patents
- Potential for subsequent patents
- Complement to an existing portfolio
- Evidence of patent infringement
- Ownership of the invention
- Plans of the inventors (stay or leave, interest in further development)
- Evaluation of the technology according to the invention - unique selling propositions:
 - complements, replaces.... known technologies
 - better compared to known technologies: faster, more efficient, simpler, cheaper, more stable...
 - merely another technology with comparable good properties (me too product)

Market potential

- Estimation of the markets that can be reached
 - What could the product/service look like?
 - Which market sector is being addressed?
 - If applicable – in which risk class is the product to be classified?
 - how large is the market overall and how is it developing?
 - (medical) need?
 - how large is the potentially achievable share of the technology (al-playing field, competing products, freedom-to-operate, etc.)?
 - Who are potential commercialization partners?
 - Is spin-off an option?
- Estimation of expected potential revenues vs. patenting costs
- Individual aspects (strategic, political...)



Assessment of patentability and patentworthiness result in a protection strategy, which is individual for each case

What can be protected by a patent?

- compounds (chemical substance, protein, drugs)
- new compositions (known compounds but different dosage amounts or forms)
- uses (use of a protein, drug; also new uses)
- biochemical processes (which modulate compounds)
- production processes (new methods of making)
- procedures and methods (diagnostic procedures)
- software with technical characteristics/Hardware
- genetically engineered products
- modified organisms, animals or plants

Any exemptions?

Not patentable are:

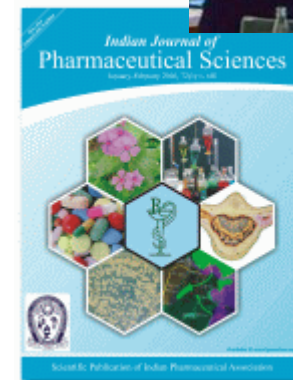
- scientific theories
- Discoveries (such as gene sequences without known function)
- plans and blueprints
- algorithms and calculation rules
- software without technical characteristics
- the human body or parts thereof
- clinical therapies (patentable in the USA)
- inventions, which offend the “ordre public” or are immoral (e.g. human embryonic stem cell debate)


When is an invention disclosed?


Before Patent application please avoid written or oral communications like

- Paper
- Abstract
- Poster
- Bachelor-, Master- or PhD-thesis
- Presentation
- Research proposals on Website
- News of research results in social media

➤ **Patent First, Publish Later!**






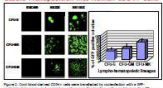


Robust Stable Gene Transfer in Hard-to-Transfect Vertebrate Cells *in vivo* by Hyperactive Sleeping Beauty Transposase

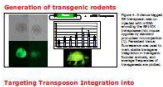
Transposon vs viral gene delivery



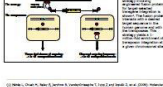
Stable Transposition into Human CD34+ Cells



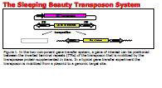
Separation of transgenic rodents



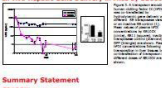
Targeting Transposon Integration into predetermined Genomic Regions



The Sleeping Beauty Transposon System



***In vivo* Hepatic Gene Delivery in Mice by SB100X**



Summary Statement

SB100X supports:

- long term stable gene transfer in hard-to-transfect cell lines
- 25-50% stable gene transfer in CD34+ hematopoietic stem/progenitor cells
- long-term engraftment and homeostatic maintenance in transgenic rodent models
- sustained (> 3 year) expansion of physiological levels of Factor IX upon transposition in the mouse liver *in vivo*
- efficient generation of transgenic vertebrate models
- efficient generation of transgenic vertebrate models
- high-producer cell lines

Partnership opportunity

- in-house of SB100X as tool
- collaboration opportunity for developing applications in different fields of use
- access to broad know-how and transposon related technologies through collaboration

Patent Situation

- pending patent applications in EP, US, CA, JP, AU

Who is an inventor?

In the European Patent Convention an Inventor is not defined

- Individual that provides an unknown solution or use in a technical field through a creative process

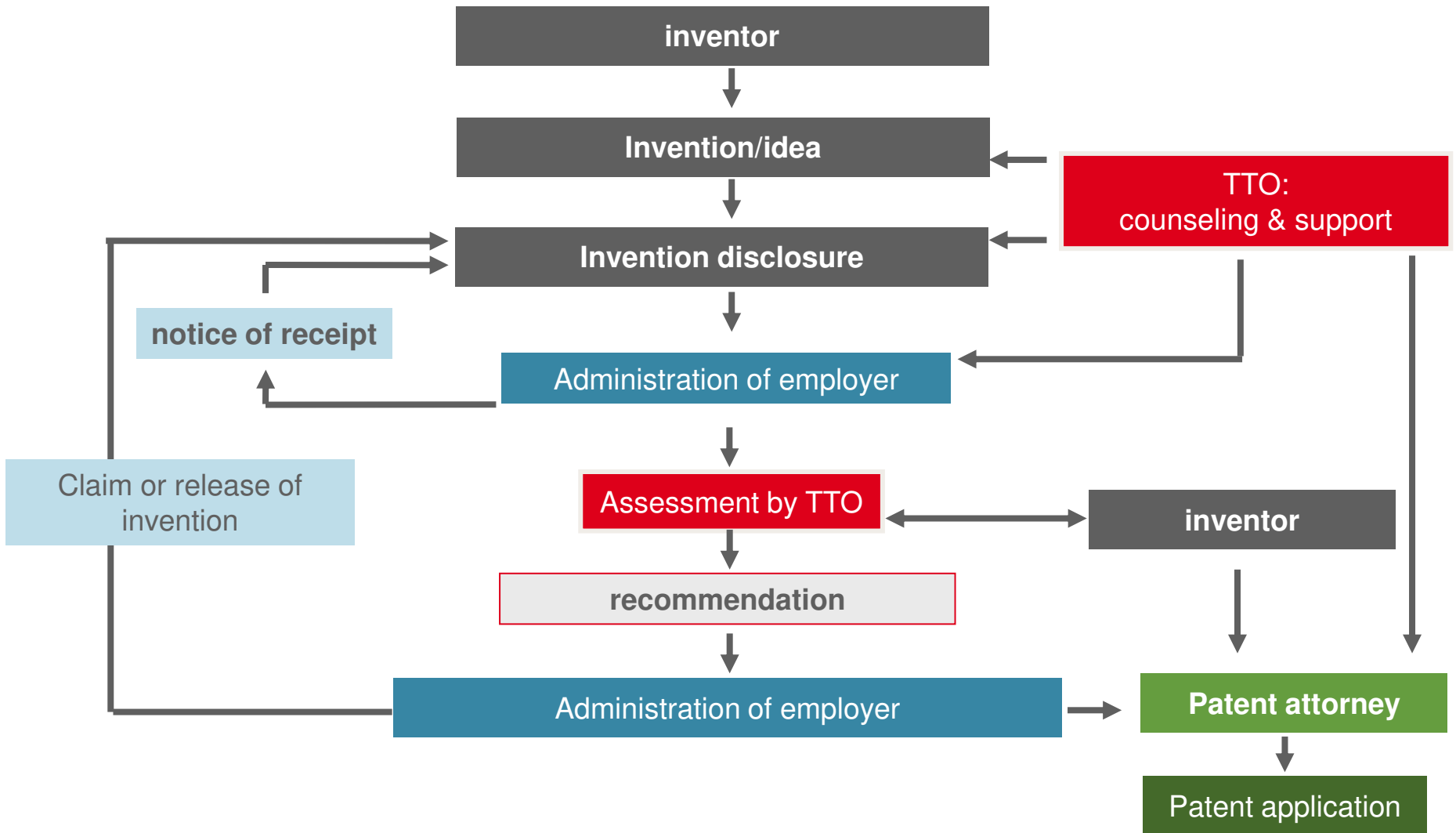
In USA

- an inventor is the one with “intellectual domination” over the inventive process and contributes to the claims of a patentable invention, and not merely one who assists in its reduction to practice.
 - “conception“
 - “reduction to practice“

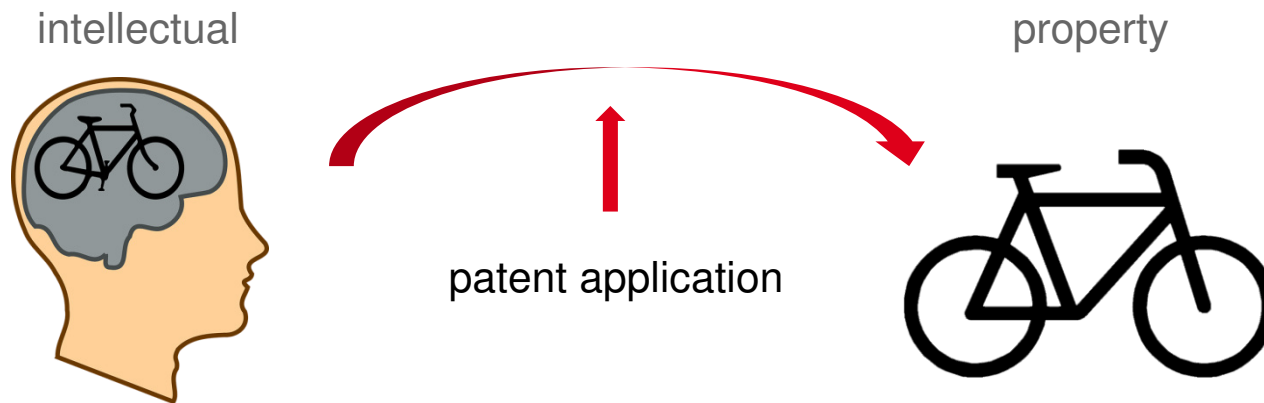
Who owns the rights in an invention?

- As a basic principle the inventor owns his invention (ArbnErfG) But....
- As an employee the inventor has to disclose his invention to his employer immediately (invention disclosure).
- Is the invention a service invention (generated while fulfilling the employee's duties) then the employer has the right to claim the invention (Inanspruchnahme).
- Is the invention no service invention (not in context of the employee's duties) , then it is a free invention and the inventor can proceed with it at his own discretion.

Process from invention to patent



Intellectual Property Right (IP Right)



- Intellectual property is a “strong” right (Art. 14 GG)
- Prohibitive right (injunctive):
 - prohibit others making, offering, putting on the market or using, importing or possessing patent protected product/method in the territory
- Patentability and scope of protection have to be distinguished
 - Patentability is based on state of the art
 - Scope of the IP right is determined by the granted claims

Patent application: national or regional

National Application e.g. German, US, GB etc.

Filing in any language

- German Translation must be filed within 1 year
- Relatively cheap
- First office action within about 10 months

Regional Application e.g. European Patent Application

- One application for:
- 38 contracting states and 2 extension states
- One Search and Examination for all states
- One annuity fee (per year) until grant for all states
- Languages: German, English, French
- Must be validated and translated in some countries after grant

Patent application: international

International Patent Application

(PCT-Application)

An option to file patent applications in all PCT **156** Member States

Preliminary Proceedings !

- Search + Opinion
- Examination (Non-binding for any state)
- No Grant of Patent
- No Opposition Proceedings

Subsequent Nationalization in any desired PCT-Member State

Granting procedure (EP)

Search:

- Search Report + Opinion; different documents considered to be relevant.
Category x: citations indicate lack of novelty or inventive step.

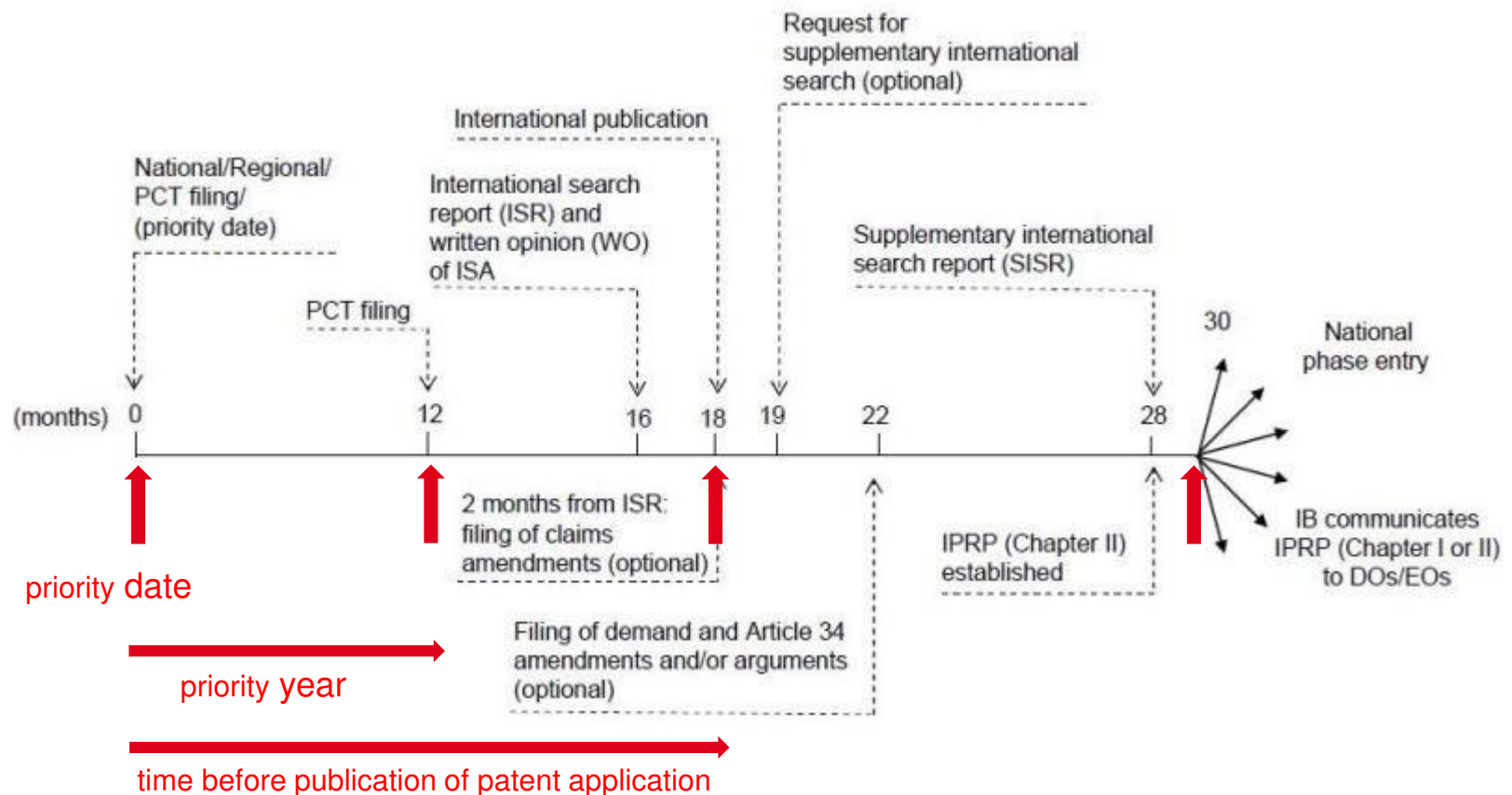
Examination:

- 1-3 Examination Reports
- Amendment of claims and description
- grant or revocation

After Grant:

- national Phases in some countries
- Opposition Proceedings

Patenting timelines



Is there a time limit for patent protection?

- Patent protection ends **20 years** after the priority filing date
- But the time for market exclusivity can be extended in special cases

| Time | |
|-----------------|---|
| 1 year | priority year |
| + 20 years | usual patent term (starting from priority establishing filing date) |
| + 5 years | Supplementary Protection Certificate |
| 26 years | maximal patent term |

- in the US for Orphan Drugs **7 years** of market exclusivity are granted
- according to the GAIN Act **5 years** of market exclusivity are granted for novel first in-class antibiotics (GAIN Act)



What is IP?



From invention to patent



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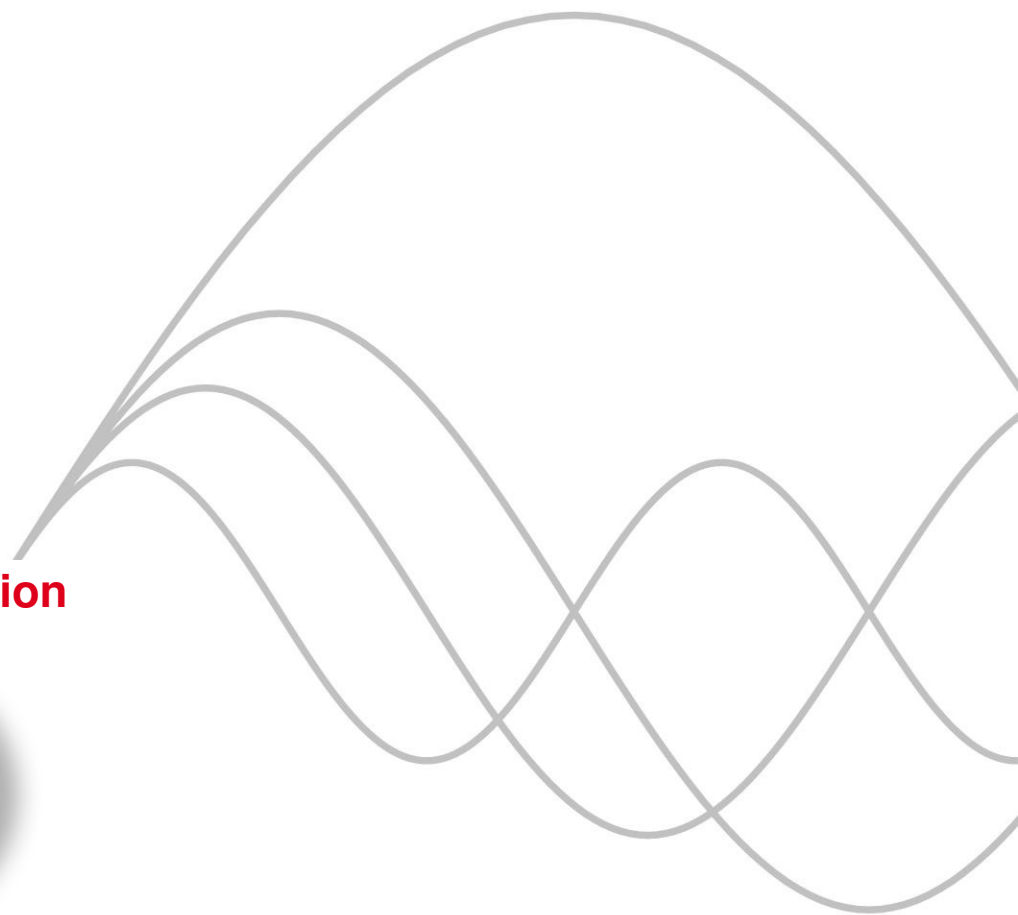


Patent exploitation



Invention

Innovation



What is Technology Transfer (TT)?

Technology Transfer means transferring scientific findings:

- Scientific results
- Know-how
- Technologies
- Products and product developments
- Procedures

from one organization to another for the purpose of further development and commercialization by means of

- Publications
- Presentation and communication, e.g. Workshops, conferences, fairs
- Exchange between experts (Know how)
- Material transfer
- Co-operations
- Application and prosecution of IP rights
- Licensing (and sale) of IP rights and Know-how
- Equity and Spin-offs

Agreements – why?

First task of academic institutions:

- Gain new knowledge and to disseminate it
- Knowledge as well as materials and techniques in life sciences have a broad range of possible applications: therapeutics, diagnostics, formulations, research tools...

Second task:

- Know-how, materials, techniques and inventions have to be protected
 - in an appropriate way – to enable commercial technology transfer.
 - Early disclosure of inventions/technologies prior to patent protection sometimes necessary
-
- Confidential Disclosure Agreement (CDA):
the appropriate tool to protect your knowledge
 - Material Transfer Agreement (MTA):
the appropriate tool to protect your materials

Want to tell someone external about your ideas ...?



This is Chris from Company XY

He is interested in your incredible interesting new research data that you just presented at the annual meeting



He invites you to having a beer because he still has some questions which he would like to discuss with you.....

Good night !

He tells you that XY is working in exactly the same field and that there might be a good chance to cooperate

Confidentiality Disclosure Agreement (CDA)

Exchange of unpublished and confidential information with third parties requires a CDA !!!

- When is a CDA required?

When you interact with partners for a potential research collaboration especially from industry and talk about unpublished results

- What are “confidential documents”?

Unpublished documents such as: experimental raw data, manuscripts, patent applications, ppt-presentations, etc.

- Formal handling procedure:

Confidential documents should be marked on every single page with the term “confidential”

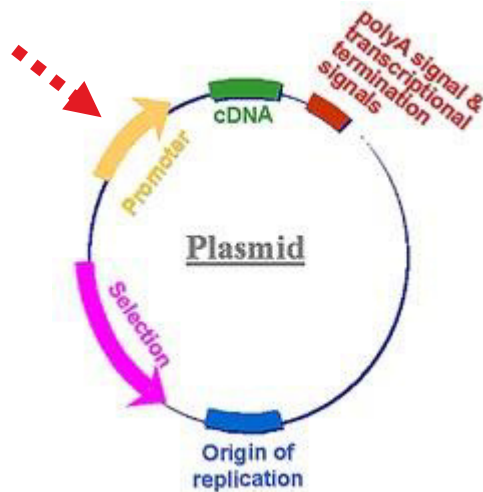
Close a CDA before you start talking !!

Confidential Disclosure Agreement CDA – why?

- to prevent disclosure and (!) use of proprietary information of the disclosing party by the recipient of such proprietary information
- to define a period for confidentiality obligations
- to define law and place of jurisdiction for any conflicts between disclosing party and recipient
- to get rid of any warranty and liability obligations (as permitted by law) relating to the use of the confidential information by a third party

Transfer of Materials and Know-how

Example: Your research collaboration involves exchange of material



This is your novel inducible promoter construct that features absolutely tight control of expression



Material Transfer Agreement (MTA) – why?

- The transfer of materials is very important to disseminate tools and reagents among the scientific community.
- Scientists are even obliged to transfer materials after publication of such materials.
- Materials can be protected either by patents and/or by transfer under a Material Transfer Agreement (MTA)
- MTA is required whenever you transfer material to third parties for research purposes
 - biological material: bacterial strains, viruses, cell lines, animals, plasmids, proteins, antibodies, blood or tissue samples, etc.
 - technical devices, chemicals, etc.

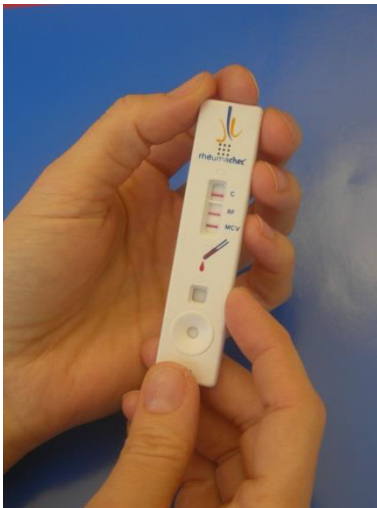
Always close a MTA before you transfer material !!

Material Transfer Agreement – MTA – why?

- to keep control of the material
- material remains providers property
- no commercial use or commercialization of the material by the recipient
- no further transfer to any third party
- to be acknowledged as source of the material in subsequent publications
- to get rid of any warranty and liability obligations (as permitted by law) relating to the use of the material by a third party e.g. forbid any use in humans

Want to evaluate your novel biomarker?

Example: You have developed a biomarker and clinicians from hospital XY want to test this device.



Your **novel** biomarker helps to define sub-populations with good clinical outcome for a special therapy.

Clinicians from Hospital XY want to use your biomarker.

The clinician promises to provide you with clinical Data to **evaluate** your biomarker.

... tell him:

Fine, let us start a **co-operation**

Co-operation Agreement

- When is a Co-operation agreement required?
Co-operation agreements are required for all co-operations with industry and academia,
 - especially for evaluation and validation of technologies, proof of principle, development of Prototypes
 - new applications; new derivatives; new mechanisms
- **Co-operations often lead to new IP in the future.**
- **Ownership of future IP should be fixed before starting a co-operation.**

Co-operation Agreement – why?

Co-operation Agreements should define:

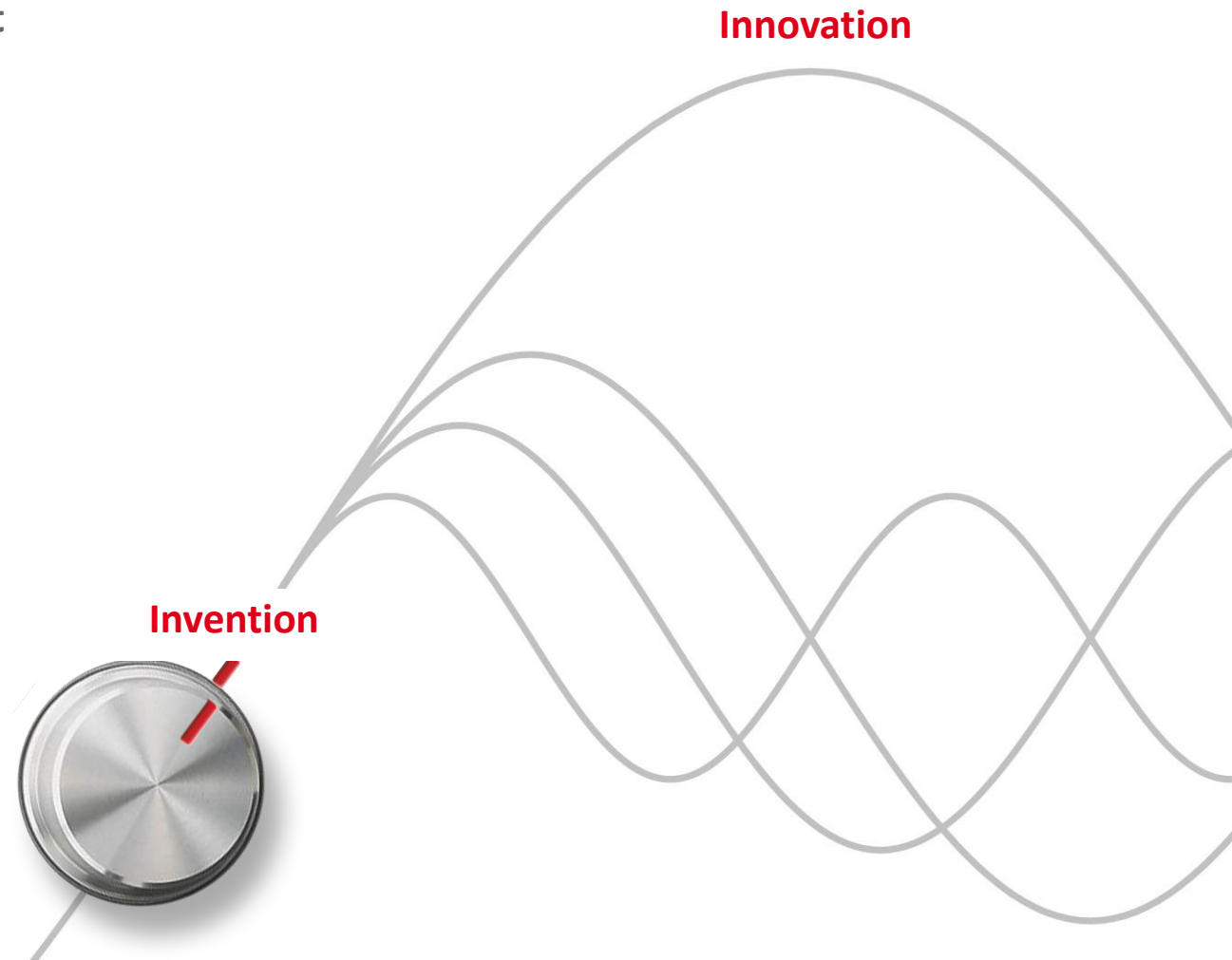
- Partner and working packages of each partner
- Timelines, costs and deliverables
- Background IP
- Use of results and Foreground-IP
- Exploitation of results and possible future licensing
- Duration of co-operation and contract
- Period for confidentiality obligations
- Law and jurisdiction for any conflicts between co-operation partners
- Exclusion of any warranty and liability obligations (as permitted by law)

What is IP?

From invention to patent

Technology transfer (TT)

Patent exploitation



Patent exploitation: What is the benefit?

For the institution

- additional income
- Return of investment

For the inventor

- Additional publications (patent applications)
- Reputation
- Additional income:
Percentage share of all revenues from exploitation of inventions or know-how

Right Exploitation Route

- For most technologies, the „right route“ for commercial exploitation can be identified.
- The main routes for commercial exploitation are
 - Co-operative further development of the technology
 - Licensing (either non-exclusive or exclusive)
 - Founding of a spin-off
 - Sale of IP
- It is dependent on the technology, market and inventor(s), which route is the best.



Right Exploitation Route

Licensing

- Licensing is still the first and foremost route for commercial exploitation.
- By licensing Licensor keeps control of the technology, which is mostly advantageous for strategic and economic reasons.
- Licenses can be exclusive or non-exclusive:
 - **Exclusive:**
 - only one Licensee with the same rights and scope of use (exclusive rights for the whole scope of applications or for a defined field and/or territory)
 - Patent costs borne by Licensee
 - Therapeutics are always licensed exclusively
 - **Non-exclusive:**
 - several partners
 - broad dissemination of the technology
 - look for more licensees, if licensee does not develop and market the technology diligently

Right Exploitation Route

Spin-Off

- For some technologies, there is an interest of the inventor(s) to take the technology and to found a spin-off company.
- However, a technology also can be the basis of a spin-off without the commitment and engagement of the inventors in such spin-off.
- Is a spin-off planned, the chances for a commercial success of such spin-off need to be assessed
- In case such spin-off looks promising an exclusive license should be granted to the spin-off (if necessary for the success of the spin-off)

Right Exploitation Route

Co-operations

- Most inventions are at a very early stage, that a partner is needed for the development into e.g. a product.
- Such partner could be an academic institution or a company.
- Frequently an industrial partner is preferred, because
 - such partner would be a suitable licensee for the technology
 - such partner would be faster and more efficient in the development of the technology.
- In both cases, a co-operation contract needs to be closed, stipulating rules for handling existing IP, materials, know-how and also new results from the co-operation.

Alternatives

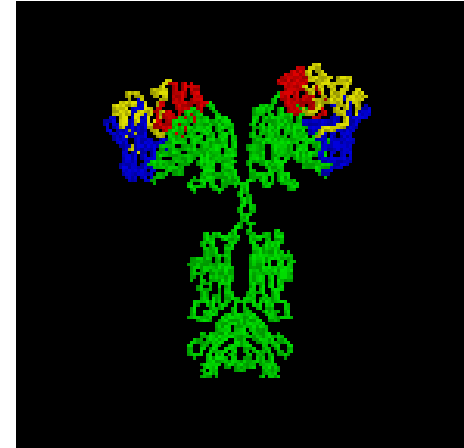
Commercial exploitation not always requires patent protection.

There are some alternatives:

- Utility model (Gebrauchsmuster, only for Germany, Japan, Austria and Hungary and not possible for processes)
- Brands/Trademarks
- Trade secret - Protection of an invention by non-disclosure:
Inventions can be kept secret by non-disclosing their subject. This is only possible, if the invention can be exploited nevertheless - typically a service or the product of a secret production process.
- Direct licensing or sale of proprietary assets:
especially for biological material, e.g. antibodies, hybridoma, cell lines, sera, animal models.... or for know-how

Exploitation without IP Rights

- Most monoclonal antibodies and animal models can be exploited without any IP protection. The long time and amount of money needed for development of such antibodies and animals inhibits copying.
- This is the case for many so called "research tools".



Summary

**Knowledge is an intangible asset,
that can be handled like a good!**

Therefore,

- Protection of intellectual property is essential,
 - By appropriate patent rights, where possible and reasonable
 - By appropriate contracts (CDA,MTA, license or co-operation agreements...)
- Protection and exploitation strategy are individually different depending on various factors