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GUIDE TO PATENTS

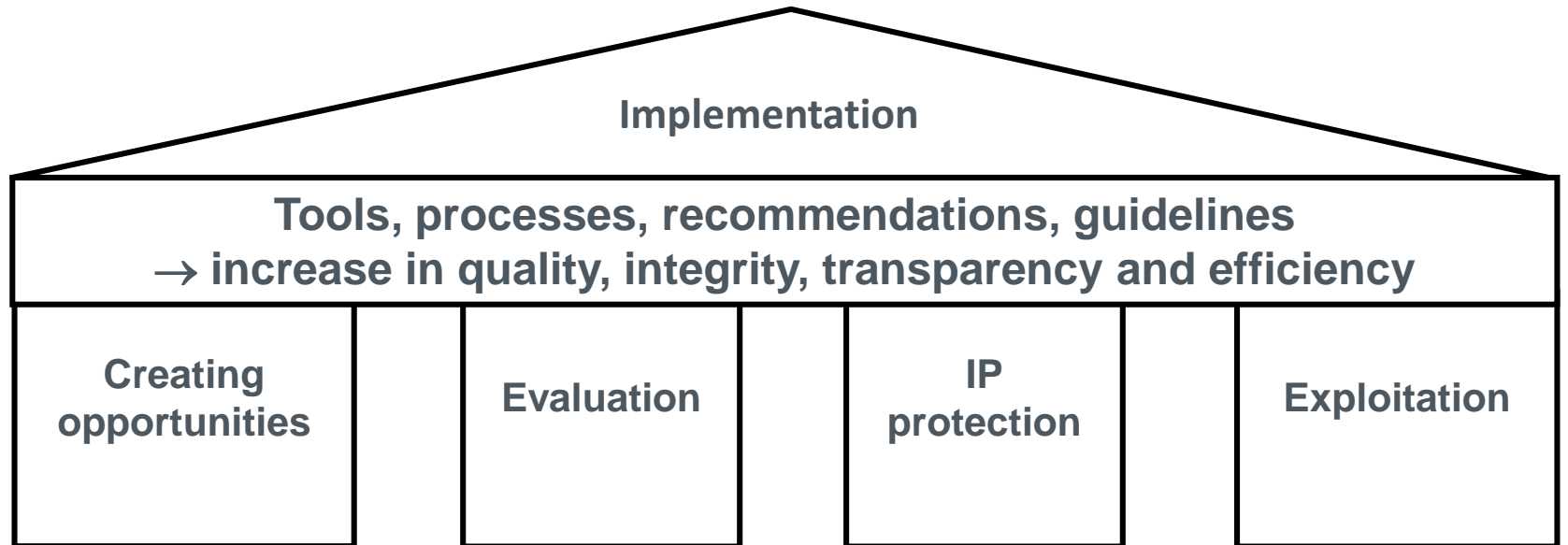
How your science/ideas make it to the patients



IP Management

GENERAL INTRODUCTION

The four main pillars of IP management



- Awareness creation
- Teaching & training
- IPR support
- Technology scouting
- Micro/seed-funding
- Innovation awards

- Affiliation
- Contribution
- Commercial Interest
- Stage of Development
- Patentability
- Value/Competitive Adv.

- Processing
- Drafting
- Filing
- Correcting
- Granting
- Contracts

- Business strategies
- Licence agreements
- Spin-outs
- Assignments/sales
- Contracts

Implementing IP management

- Tools and processes → assistance from technology transfer office
- Recommendations and guidelines → university IP policy

IP policies at MUI

- Recording of inventive concepts and results
- Preserving confidentiality of information
- Determining inventorship and ownership
- Publications
- Reporting of inventions
- Assessing third-party rights
- Reward system

Tools and processes

- Confidentiality → Non-disclosure agreements
- Capture → Lab notebooks/work journals
- Reporting → Invention disclosures
- Protection → IPR (patent, design, copyright...)
- Collaborations → IP provisions in contracts

Notebooks and work journals

- "Good practice" record of research or creative work
- Critical to addressing many concerns, including:
 - data to support patent applications
 - inventorship and ownership
 - data and procedures for regulatory purposes
 - contractual obligations
 - know-how relating to licence deals and IP assets of spin-outs

The invention disclosure form

- Important document for MUI and inventors
- Information requested is designed to help:
 - evaluate patentability and commercial potential
 - determine inventorship and ownership
 - assess possible third-party rights
 - provide information for patent attorneys (inventive step and novelty)

Proprietary information

- Take advice on the timing of your publication
 - Does it contain information relevant to a patent application?
 - Will it be published before a patent application is filed?
 - Should you withhold certain information?
- Take precautions regarding disclosure and receipt of confidential information and materials
 - Disclosure or receipt of information → non-disclosure agreement
 - Material transfers → material transfer agreement

Collaborations/Contracts

- Definitions of IP used and created in the project
- How it will be managed
- Ownership and access rights
- Ownership and access to improvements to IP
- Who will file and prosecute patents
- Sharing of costs, risks and returns
- Terms for publications

IP STRATEGY

IP strategies for universities and businesses

- Universities
 - teaching
 - fundamental and applied research
 - technology transfer (i.e. no in-house production and sales)
- Businesses
 - own development, manufacturing and/or sales of products and services
 - commercialisation of technologies (out-licensing, IP sales)

IP strategy approaches

- Developing and protecting IP
 - particularly relevant to university activities
 - also relevant to businesses
- Creating a competitive advantage by optimising and using IP
 - relevant to university spin-out companies
 - relevant to businesses

Developing and protecting IP

Strategic objective	Tactic
"Monopolising" the technology	<ul style="list-style-type: none">– Publish and ensure wide access, or– Protect with patents and other IP forms, or– Maintain as secret know-how
Managing the IP filing strategy	<ul style="list-style-type: none">– Maintain application for a limited duration– Decide which territories should be protected
Enhancing the status of the technology	<ul style="list-style-type: none">– Develop complementary technologies– Create portfolio of related patents & other IP

Creating a competitive advantage

Strategic objective	Tactic
Creating a “monopoly”	<ul style="list-style-type: none">– Be aware of IP landscape (competitors)– Ensure freedom-to-operate– Police infringers– Defend "monopoly"
Managing competitors	<ul style="list-style-type: none">– Create defensive patents– Trade IP for cross-licensing deals
Securing finance	<ul style="list-style-type: none">– Build IP portfolio to attract investment
Monetising the IP portfolio	<ul style="list-style-type: none">– Consider out-licensing, sale of IP, spin-outs
Sourcing new IP	<ul style="list-style-type: none">– Use collaborations, in-licensing, acquisitions

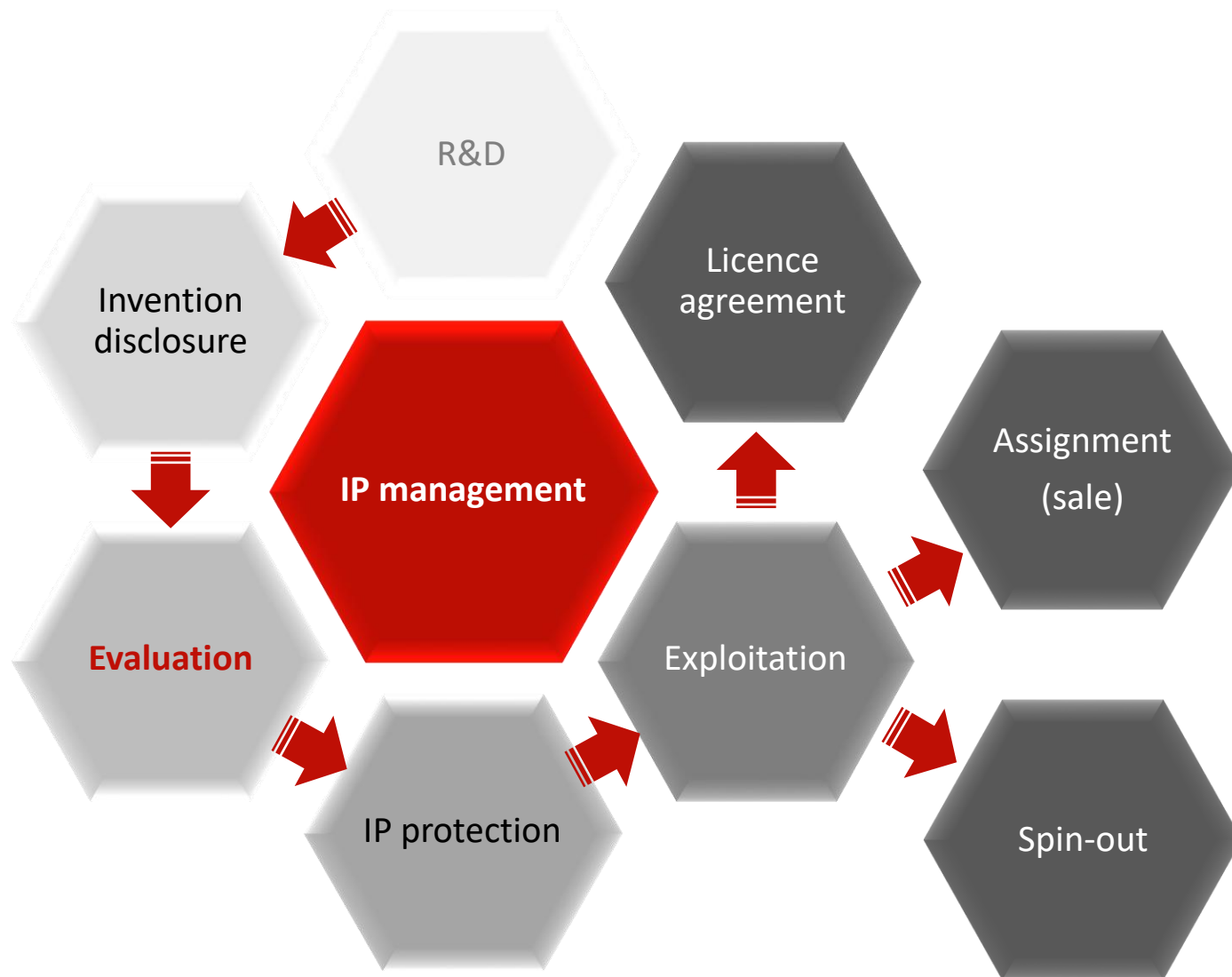
COMMERCIALISATION OF IP

Technology transfer

- University objective
 - to make innovative research results and technologies available for wider use by means of technology transfer

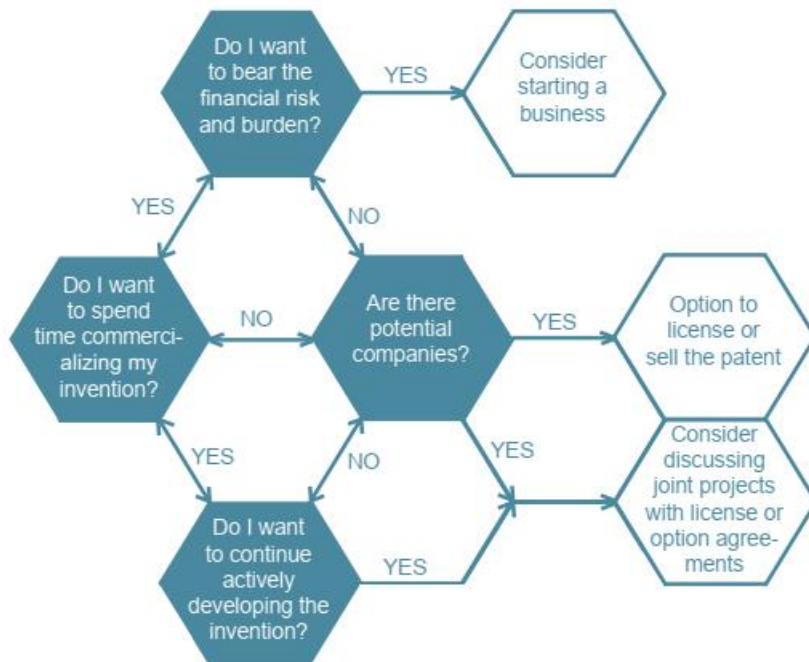
- Possibilities for technology transfer
 - publications, people and artefacts
 - collaborations
 - contract research
 - licensing
 - sale
 - spin-outs

How universities can exploit IP



Technology Transfer

Navigating your Journey



Not sure?
Your TTO is happy to meet you and discuss options

Routes

Licenses

Most often, the University makes technologies available to companies by licensing intellectual property. A company receives the right to use the technology in return for appropriate remuneration.

Sales

In some cases, the University transfers ownership of its intellectual property to companies, usually in return for lump sum payments.

Cooperation Projects

Cooperation projects with one or more companies are an option to exploit research results and gain access to their expertise. Your TTO supports project planning, assessment of IP rights and establishing of suitable agreements.

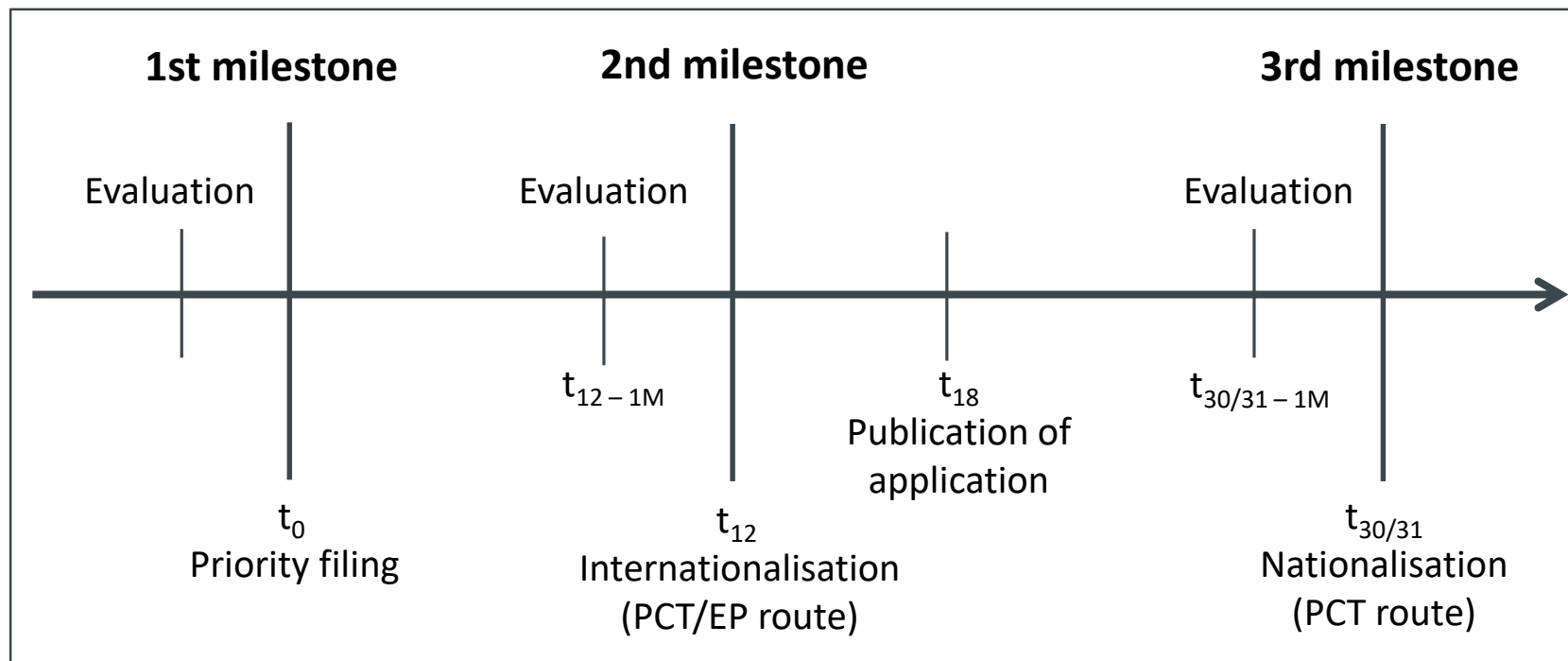
Creating a New Business

An invention alone is not enough to build a successful company. Your TTO supports you through forming a spin out, providing exposure to useful networks in private sector and industry and start-up activities, as well as consulting on project- and business plans.

Evaluating IP

- Legal status
- Technology
- Market conditions
- MUI Status / Budget

IP evaluation process

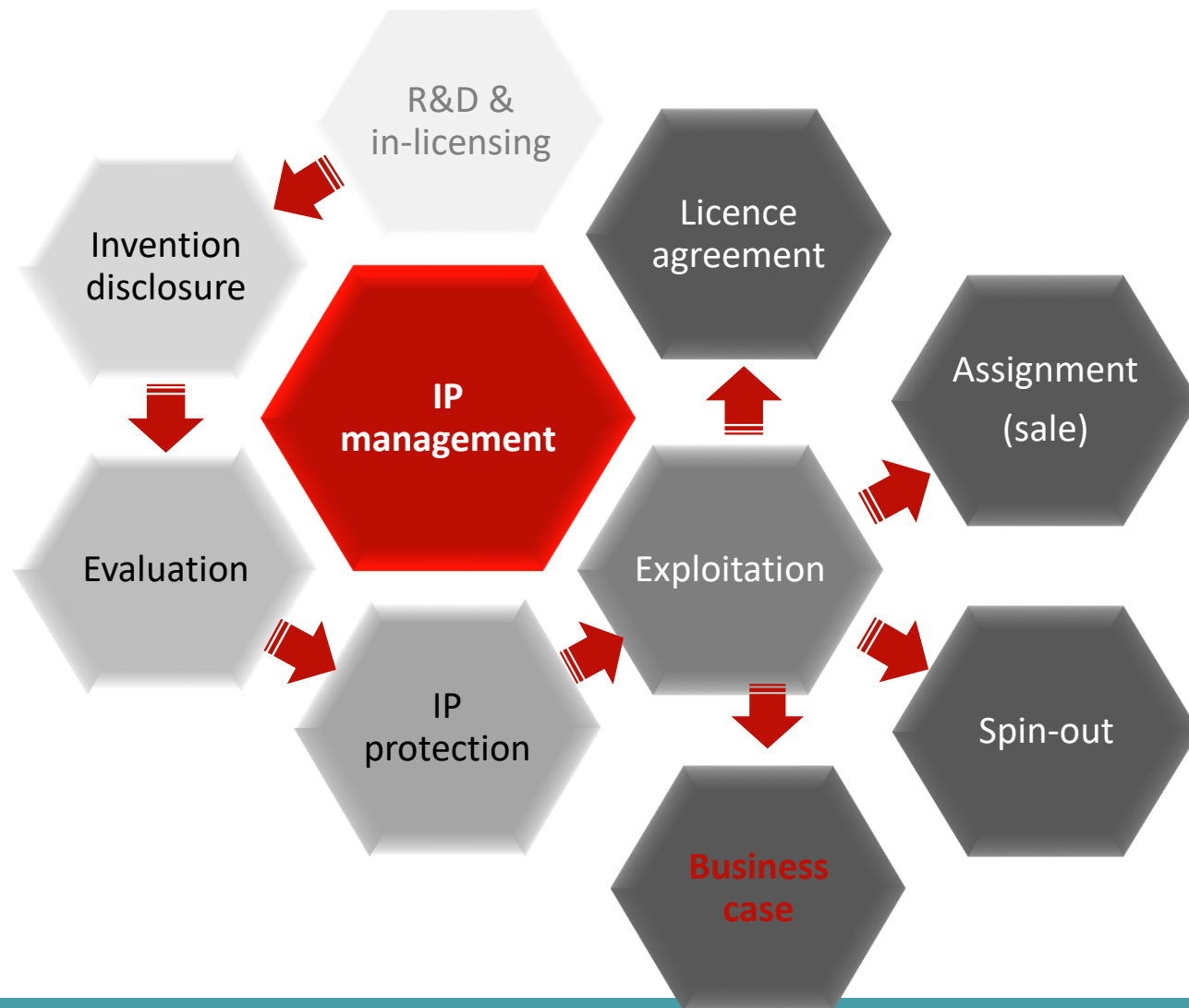


t_0 Patent priority filing: start of priority year

t_{12} Deadline for internationalisation: 12 months after t_0

$t_{30/31}$ Deadline for nationalisation: 30/31 months after t_0 (PCT route)

How businesses exploit IP



Licensing IP

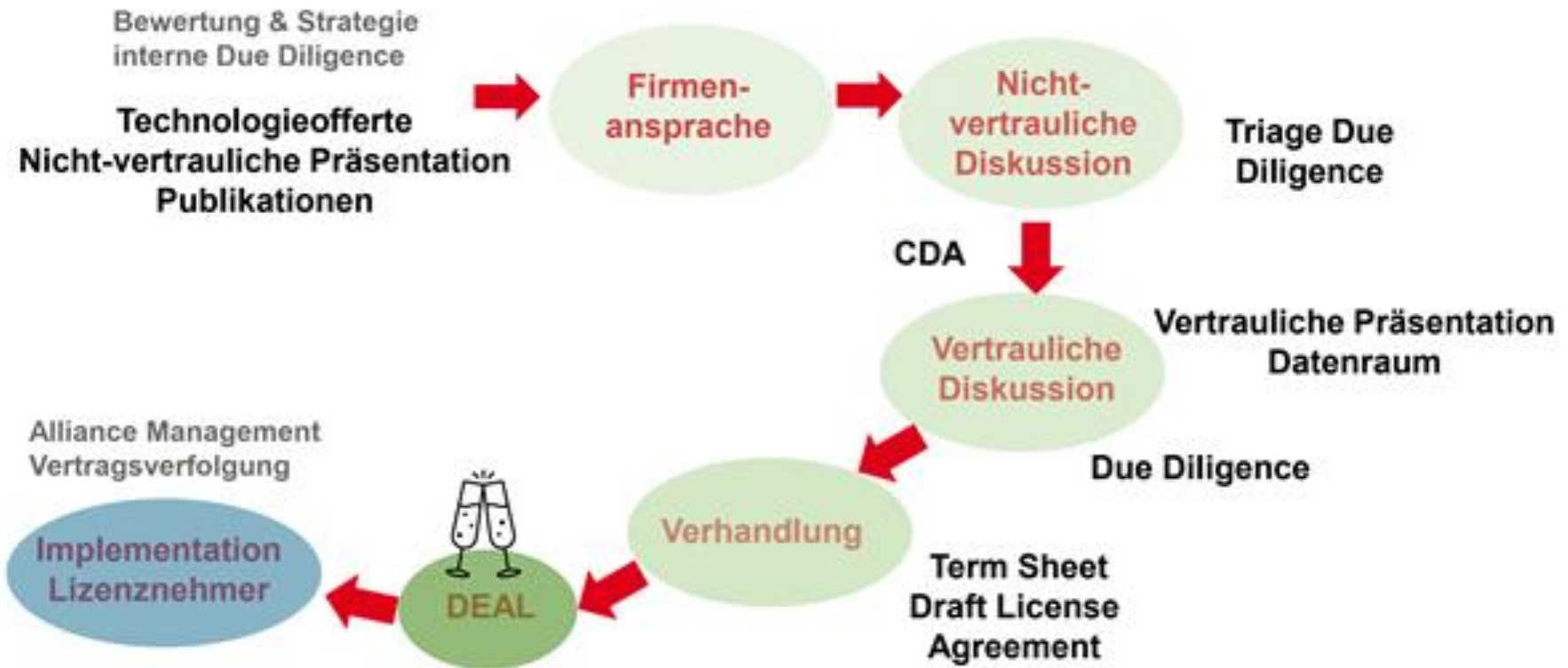
- Intellectual property rights
 - prevent others from using your inventions and creations
- Licences (contractual agreements)
 - allows others to use your inventions and creations
 - in accordance with specific terms and conditions
- Requirements for a legal contract
 - mutual exchange of a bargain
 - consideration (payment) exchanged for something of value (IP)



Benefits of licensing

Licensor	Licensee
<ul style="list-style-type: none">▪ Create new source of revenues▪ Access new territories and markets▪ Influence market acceptance for technology and products▪ Create production and supply partnerships	<ul style="list-style-type: none">▪ Gain access to new technologies, turn-key products and processes and new markets▪ Reduce or avoid R&D costs and associated risks▪ Provide competitive advantage and IPR protection▪ Increase asset value of business

Overview Licensing Process



IP and spin-outs

- Decision to set up university spin-outs and new technology start-ups relies mainly on:
 - A demonstrated technology
 - Good commercial potential
 - Validly protected IP position
 - Strong management skills and expertise

- Investment
 - Start-ups generally lack positive cash flows.
 - Value lies in IP assets.
 - Investors base decision on strength of team and IP to protect future earnings.

IP MANAGEMENT CASE STUDY

Background

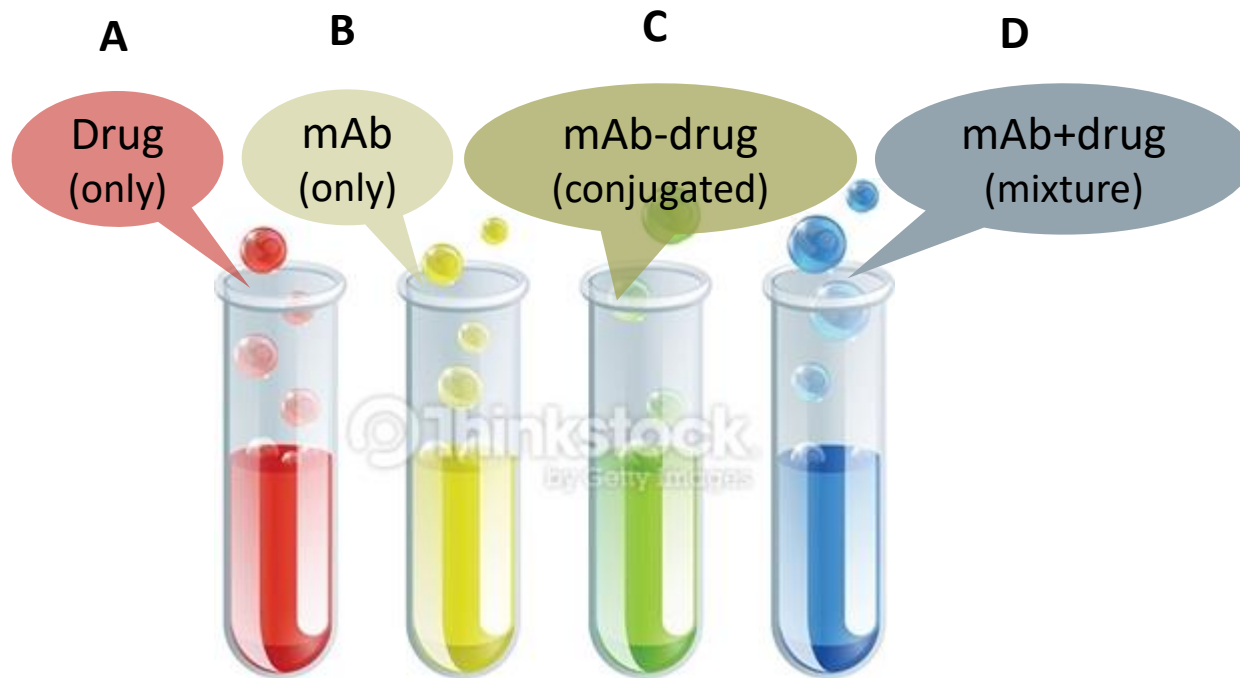
- Scientists at the Weizmann Institute conduct research on using antibodies as carriers to target treatment for specific cancers.
- A former colleague provides materials for use in experiments.
- Promising results are obtained.
- A patent application is filed.
- The patent is licensed to a biopharma company.
- Ownership of the patent is disputed.
- Litigation proves costly.

The research programme

- Objective: to target cancer cells with a chemotherapeutic drug.
- Sela's research group at the Weizmann Institute received two monoclonal antibodies (mAb) from former colleague Professor Schlessinger.
- mAb binds to specific site on cancer cells (selective targeting).
- One mAb selected for experiments.
- Drug chemically linked to mAb (conjugated).
- Effects targeted delivery of chemotherapeutic drug.

The experiments

Treatment of tumour with mAb and chemotherapeutic drug



A = some effect

B = some effect

C = some effect

D = significant inhibition

The results

- Expectation that **experiment C** would show best results
 - mAb should carry drug directly to tumour and destroy cancer cells.
- **Experiment D** shows a surprising effect
 - Free mixture of chemotherapeutic drug and mAb creates synergistic effect on inhibiting growth of cancer cells.
 - Unpredicted result demonstrates "inventive step".

The publication

- Sela did not consider filing a patent application
 - mAb owned by Schlessinger's employer, Rorer Biotechnology.
 - Might give rise to complex negotiations.
 - Happy to disseminate results in *Journal of the National Cancer Institute*.
- Sela's group prepares publication
 - Draft of paper shown to Schlessinger on next visit.
 - Schlessinger also named as author for contribution of mAb.
 - Paper published in December 1988.

The patent application

Schlessinger discusses results with colleagues at Rorer:

- Clinical studies initiated.
- Patent application prepared.
- Claimed "antibodies" + "antibody/drug mixtures" in cancer treatment.
- Inventors named are all Rorer employees.
- US patent application filed September 1988 (unknown to Weizmann).

The licence

- 1994: Rorer grants exclusive licence to ImClone.
- ImClone invests USD 190m in developing cancer therapy.
- 1999: Aventis acquires Rorer and patent after series of mergers.
- "Erbix" receives FDA approval:
 - 2004: colorectal cancer
 - 2006: head and neck cancer
- 2007: sales of "Erbix" in the order of USD 400m per year.

The patent dispute

- 2001: Patent granted and published (US6217866):
 - US patent limited to claims for mAb/drug mixture.
 - Other territories grant claims to mAb only and to mixture.
- 2002: Sela becomes aware of patent and raises concerns.
- Yeda (technology transfer company for Weizmann Institute) enters discussions with Aventis and ImClone → no resolution.
- 2003: Yeda starts court proceedings against Aventis and ImClone.

Litigation

- Yeda's case
 - Experiments and inventive concept originated solely from Sela's group.
 - Data and figures for patent specification drawn from draft publication.
- Defendants' case
 - Provided mAb for the experiments.
 - Schlessinger advised Weizmann scientists on the project.
 - Had already contemplated mixture of mAb and drug.

The court decision

- Weizmann scientists are sole inventors of US patent.
- Inventorship of patent corrected at USPTO.
- Yeda becomes owner of patent.
- Out-of-court settlement reached 2007:
 - Yeda owns US patent.
 - Yeda and Aventis jointly own patents in other territories.
 - Aventis and ImClone pay USD 60m each to Yeda.
 - ImClone pays Yeda royalty on sales in US.
 - ImClone pays Yeda and Aventis royalty on sales outside US.

Note on inventorship

Judge Buchwald: *"Conception is the touchstone of inventorship, the completion of the mental part of invention."*

- The inventors are those who conceived of the idea of using the mAb in an unconjugated mixture in order to treat human tumour cells.
- The provision of mAb alone does not give entitlement to inventorship.
- There was no evidence of collaboration or contribution to conception or reduction to practice of the invention by Schlessinger's group.

Lessons learnt

- Exercise caution in disclosing research results → use an **NDA**.
- Clarify terms for exchange of materials → use an **MTA**.
- Complete an invention disclosure form (**IDF**) to help inventors focus.
- Keep **notebooks** to provide convincing documentary evidence.

Steps that might have been introduced in the two organisations involved that could have prevented the situation of incorrect inventorship arising



IP Inventorship/Ownership

- Inventorship is distinct from ownership
- Inventorship is distinct from authorship
- Inventorship not determined by contract. It is governed by patent law of each jurisdiction
- Ownership can be determined by contract



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Getting Support Technology Transfer MUI



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Thank you for your attention!

Questions?



Defining an Invention

The criteria for deciding who should be considered an inventor are quite different to those normally applied to determining authorship of a scientific research paper.

Define the invention (or inventions)

An invention can be any new product or apparatus, or method or process, which is properly described in the application. This can be assessed by comparing experiments, data or ideas disclosed in the patent application with previously published technology.

MUI in collaboration with Ascenion will together with the inventors define what the invention is and evaluate its exploitation potential. In case of doubt about what the invention(s) may be, the matter will be discussed with the patent agent who is drafting the patent application.



What Constitutes Inventorship

Patent law views an invention roughly as a two-step process:

- Conception
- Reduction to Practice

An idea is conceived, and the conceived idea is reduced to practice, i.e. a working example is made, or at least enough proof is presented that such a concept can be realized. Without any of these two, an invention is not patentable.



What Constitutes Inventorship

The inventors are the “actual devisers” of the invention(s) described in the patent application, “The contributed conception must be important enough to be included in a claim of the patent”, this includes anyone who:

- Conceived the initial ideas which defined the research which led to the invention;
- Actually devised the experiments or products which form the basis of the patent application;
- Carried out any experiments or other processes described in the patent application which required that person to show initiative to conceive and/or complete, for instance because unexpected practical difficulties had to be solved;
- Interpreted the data disclosed in the patent application, and recognised the significance of results.

What Doesn't Constitute Inventorship



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Not including anyone who:

- Simply carried out work under instruction (regardless of how much skill and effort this took) particularly if the work took no initiative and required no modifications to carry out as instructed;
- Had no part in the research, regardless of whether or not they funded it, were associated with it in other ways, owned the facilities which were used in the research, published earlier relevant work, or contributed very general work or assistance;
- Was a Project Manager or Supervisor but did not contribute technically to the actual invention.

Wooden Chair Example



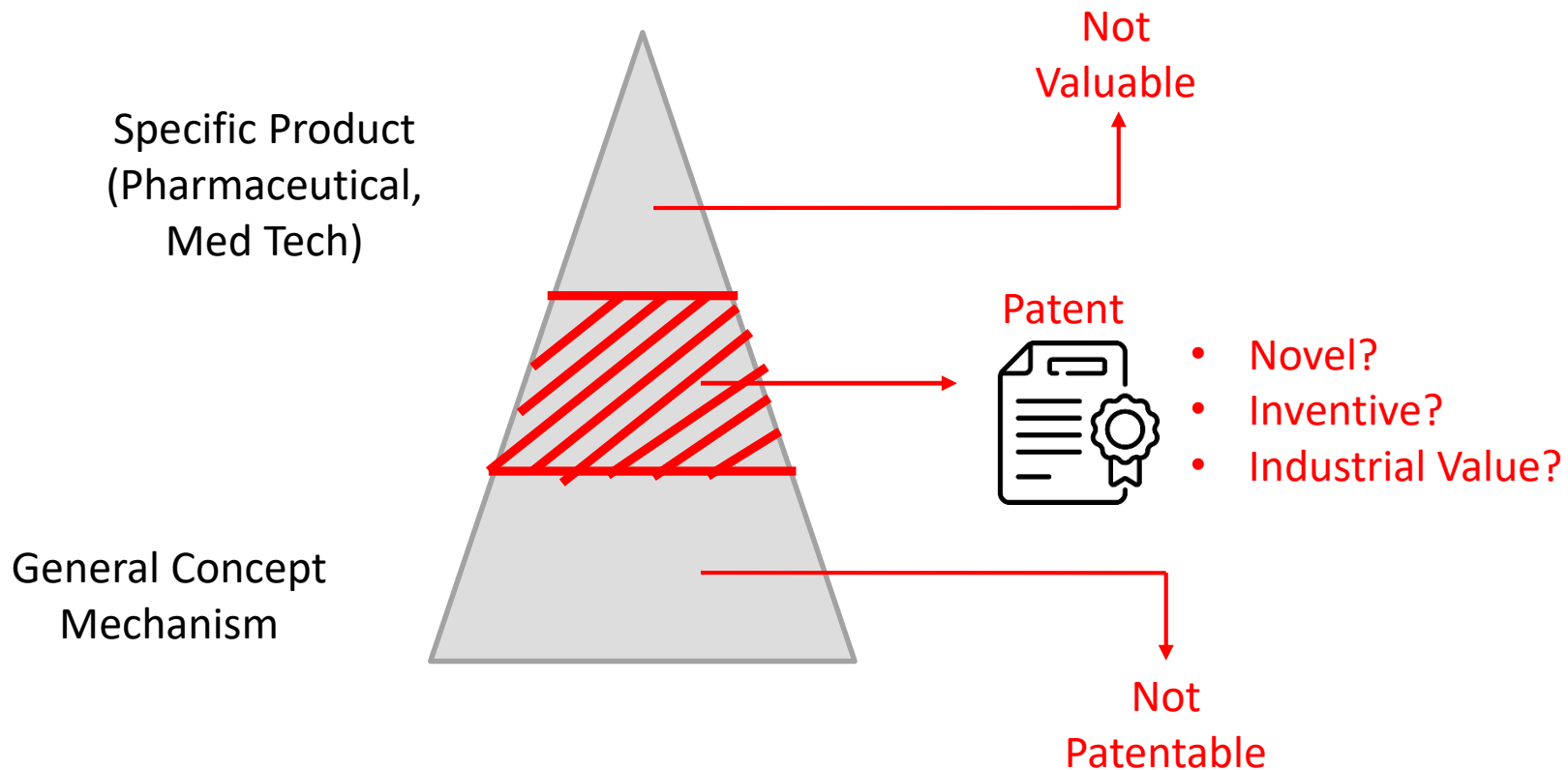
Invention: a wooden chair claiming new ergonomic arm rests.

- Carpenter not inventor
 - Inventor hires a carpenter to make a prototype chair, with detailed instructions about how the chair should be made. The carpenter suggests to the inventor that a different kind of joint commonly used in the industry should be used to secure the legs.
 - In this case, the carpenter is *not* a co-inventor because the patent claim is not about joining legs to a chair. The inventor can write in the specification of her patent application about how to fix the legs of a chair as suggested by the carpenter. But as long as it is not in a claim, the carpenter is not a co-inventor.
- Carpenter inventor
 - Carpenter's assistant suggests another way of making ergonomic arm rests by increasing the radius of one of the center boards, and using a scroll saw between layers, and the inventor likes the idea. She then adds a claim to include the assistant's idea. The assistant then becomes a co-inventor.

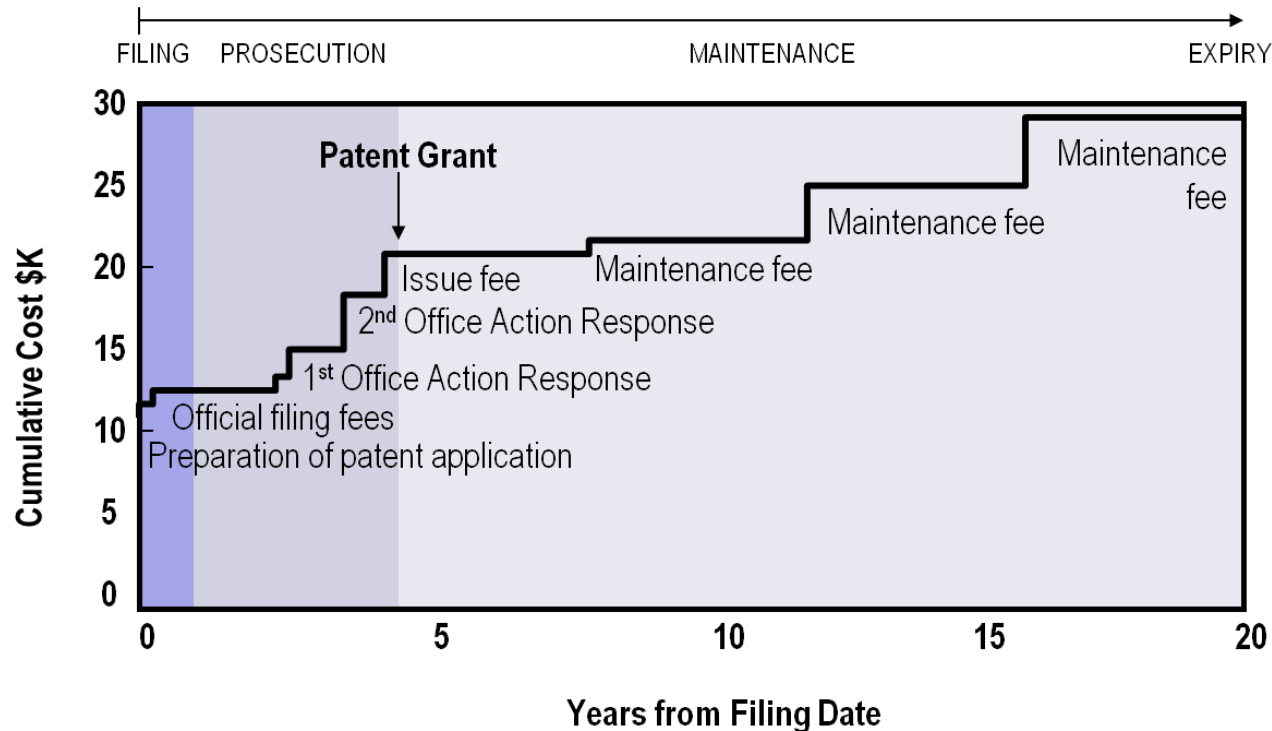
What is patentable ?



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Patenting is a substantial multi-year investment and must be planned and budgeted accordingly



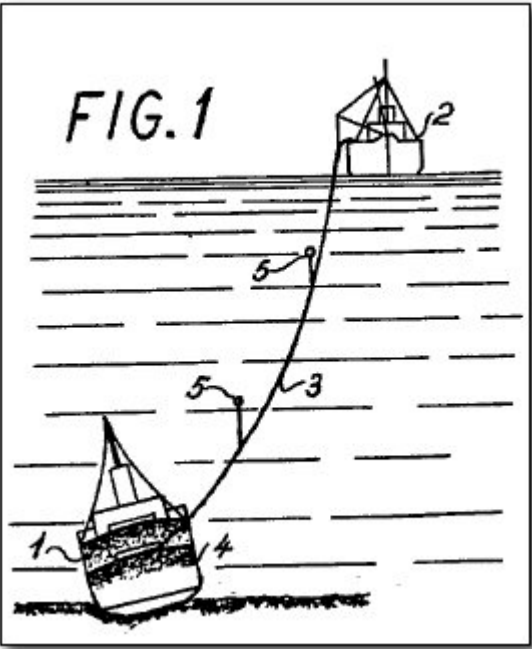
Insights for more control:



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clear map (novel?inventive?industrial application?) -> better actions

Novelty?



Insights for more control:

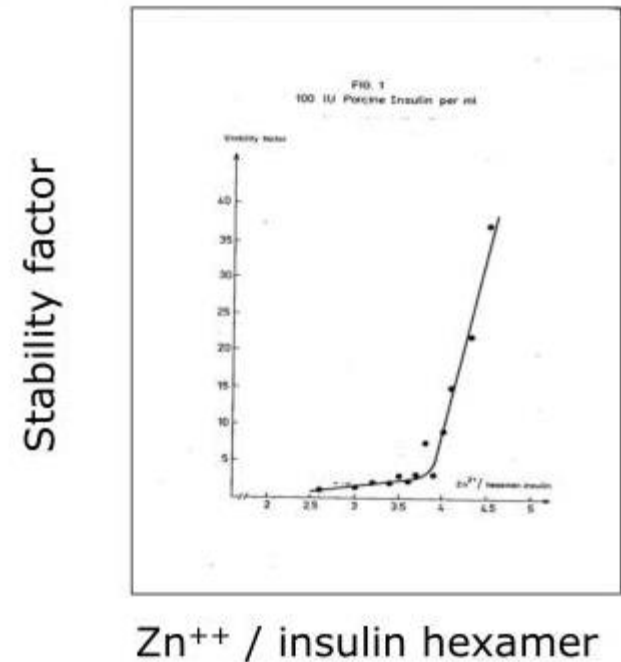
clear map (novel?inventive?industrial application?) -> better actions



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Inventive Step?

- Insulin solution characterized to comprise Zn^{2+} ions in an amount of above 4 Zn^{2+} per hexamer insulin but below the limit for precipitation
- Prior art disclosed insulin solutions with 4 Zn^{2+} per insulin hexamer



Insights for more control:



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clear map (novel?inventive?industrial application?) -> better actions

Application? Market? Where are we? Where do we want to go?

- disease identification and diagnosis
- drug discovery and manufacturing
- medical imaging diagnosis
- pharmaceutical treatment
- personalized treatment and behavioral modification,
- smart health records
- clinical trial and lab testing
- prediction of disease
- med tech

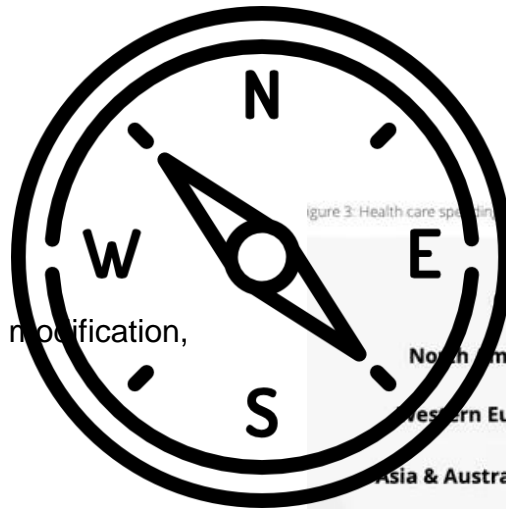
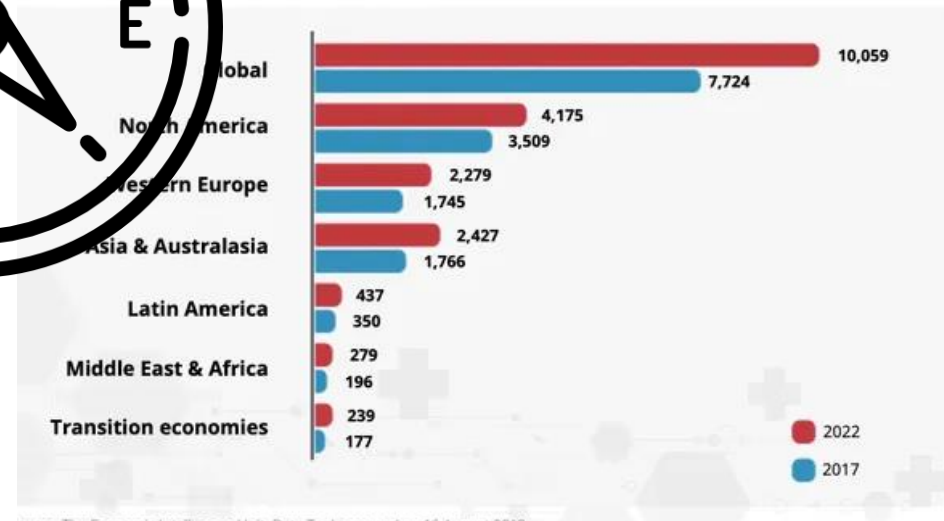


Figure 3: Health care spending (USD billion), and CAGR 2017 - 2022



Insights for more control:

Data, Trainingsets, Software - inventive?



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Technical effect /

Technical purpose?

- Goes beyond the 'normal' physical interaction between program/software and computer/hardware.

No further technical effect	Further technical effect
Flow of electric currents in the computer when running a program	Increasing the range of an electric car; controlling a vehicle with a mathematical method
Rules for an auction; hotel booking system	Digital audio, image or video enhancement or analysis
Aesthetic effects of a video; computer games	Speech recognition, separation of sources in speech signals
Algorithm to invert a matrix	Making a medical diagnosis by an automated system that processes physiological measurements