

Dr. Alexandros Papaderos

Patenting inventions

From idea to commercialisation

Commercialization of research results:
case studies from the Technical University of Munich

My first-hand experience

- ▣ studies in biology, focus on microbiology, analytical chemistry and toxicology
- ▣ 15 years in
 - protection and commercial exploitation of research results
 - university entrepreneurship
 - collaboration between academia and industry
- ▣ since 2005 Deputy Head of the Office for Research and Innovation / Head of Patents & Licenses
Technical University of Munich

Focus

- ▣ development and implementation of TUM's IP strategy
- ▣ management of academia-industry relations
 - ▣ strategic alliances
 - ▣ contract research
 - ▣ cooperations
- ▣ negotiation of contracts
- ▣ supporting the creation of start-ups and spin-offs

Agenda

- General introduction in commercial exploitation of IPR in academia
- Commercialization process
- Typical pitfalls in the commercialization of university inventions
- Case studies
 - Licensing to established companies or to spin-offs?
 - Licensing and collaboration
- Q&A Session

TUM. Dimensions 2015

13 Faculties

156 Degree Courses

~ 32 500 Students, 33% Female Students, 18% Internat'l Students

~ 10 000 First-year Students

~ 5 140 Graduates

911 Doctorates completed

~ 5 000 Publications in peer-reviewed journals

478 Professors (incl. hospital)

~ 5 800 Scientific Staff Members (incl. hospital)

~ 3 200 Non-Scientific Staff Members (not incl. hospital)

€1095 Mio Total Budget

< 1 000 Research Agreements with Industry and Academia

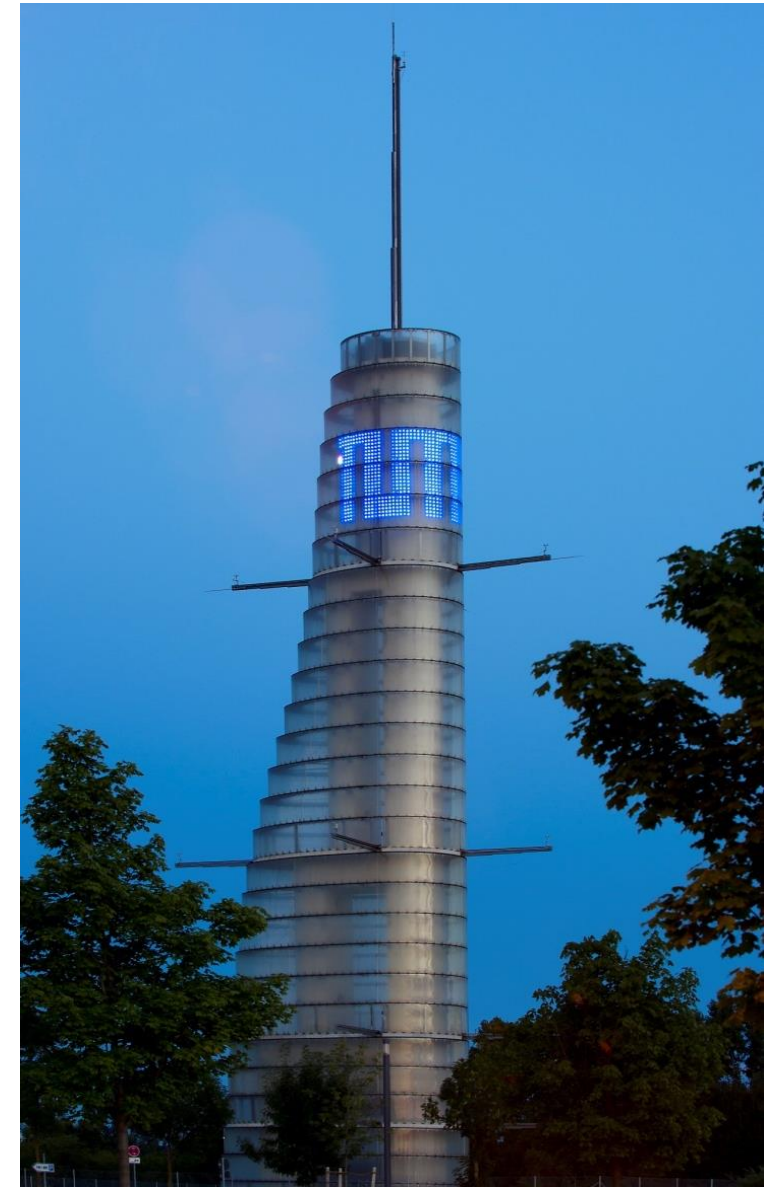
< 73 start-up and spin-off companies

178 Invention disclosures

28 Patents filed

221 Patent families

< 1,5 Mio€ IP commercialisation Revenues



University's Third Mission

as stated in the Bavarian Higher Education Law

“... act together with economic and professional practice and promote knowledge and technology transfer. “

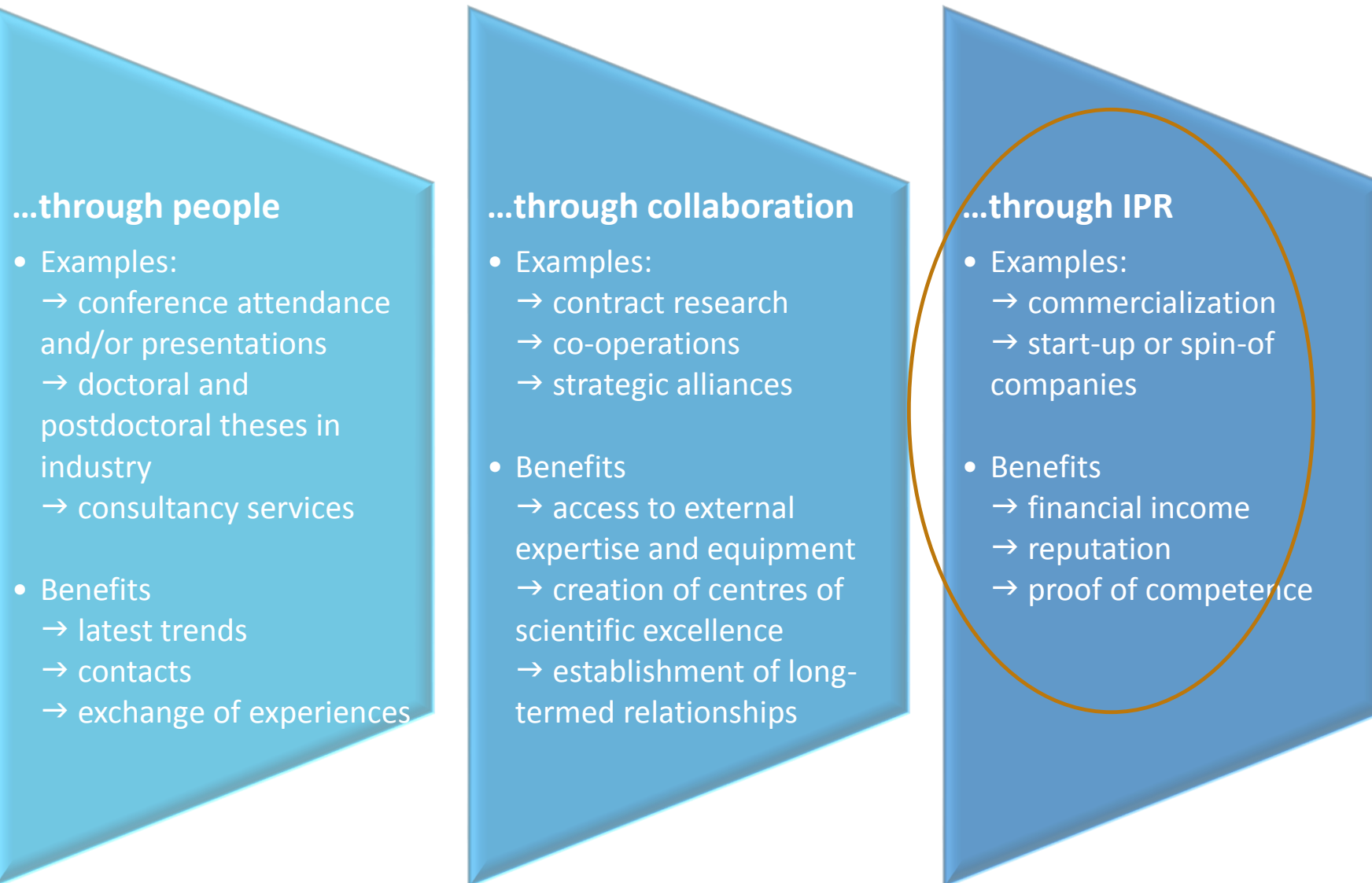
- Mission statement of TUM

“...TUM....proactively brings results from fundamental research into market-oriented innovation processes TUM initiates the founding of growth-oriented startup companies by its members and supports them...”

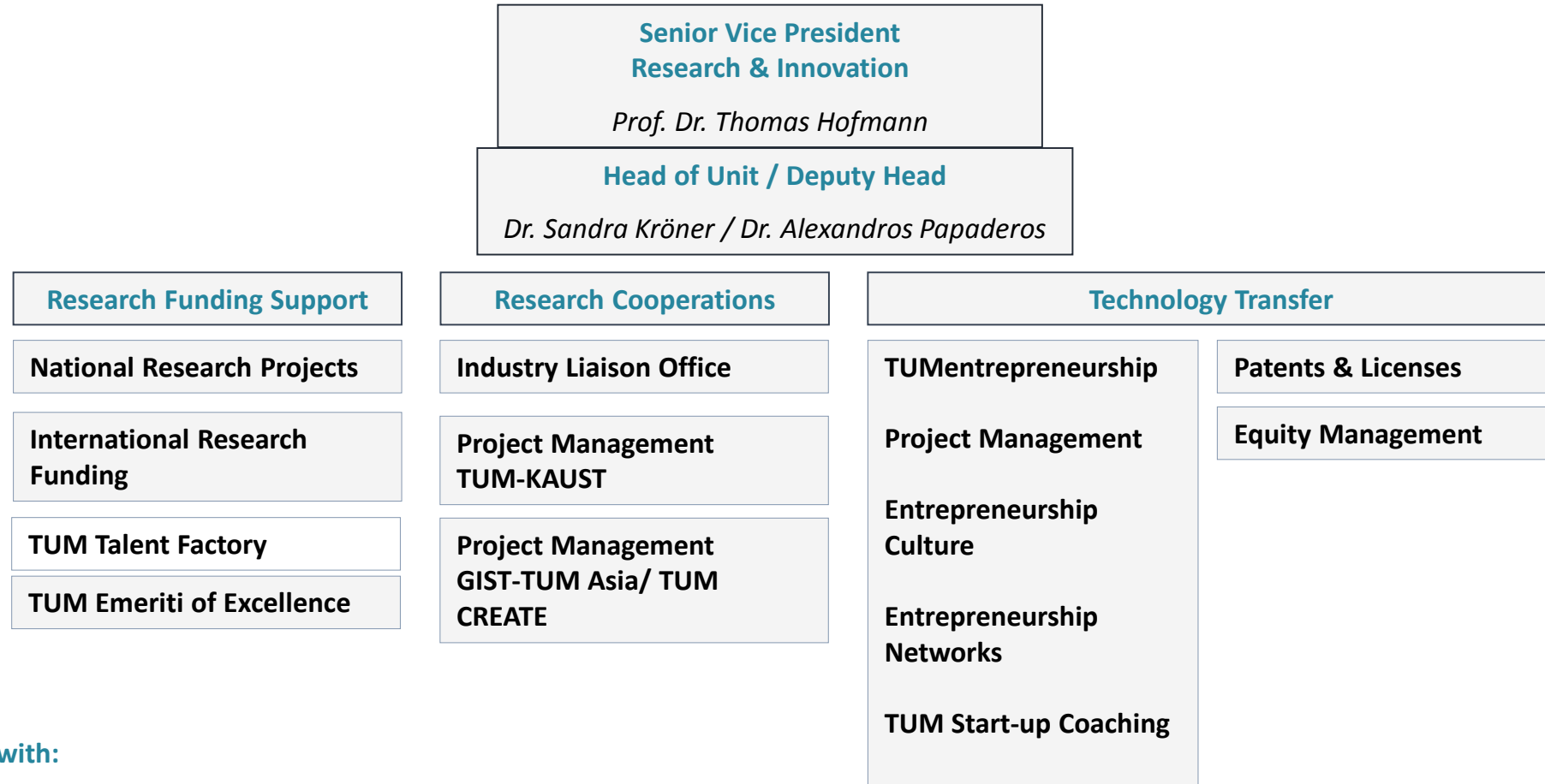
- TUM IP Policy

„...the commercialization of research results is part of the mission of TUM.“

At TUM Knowledge and Technology Transfer is made...



TUM ForTe Office for Research and Innovation



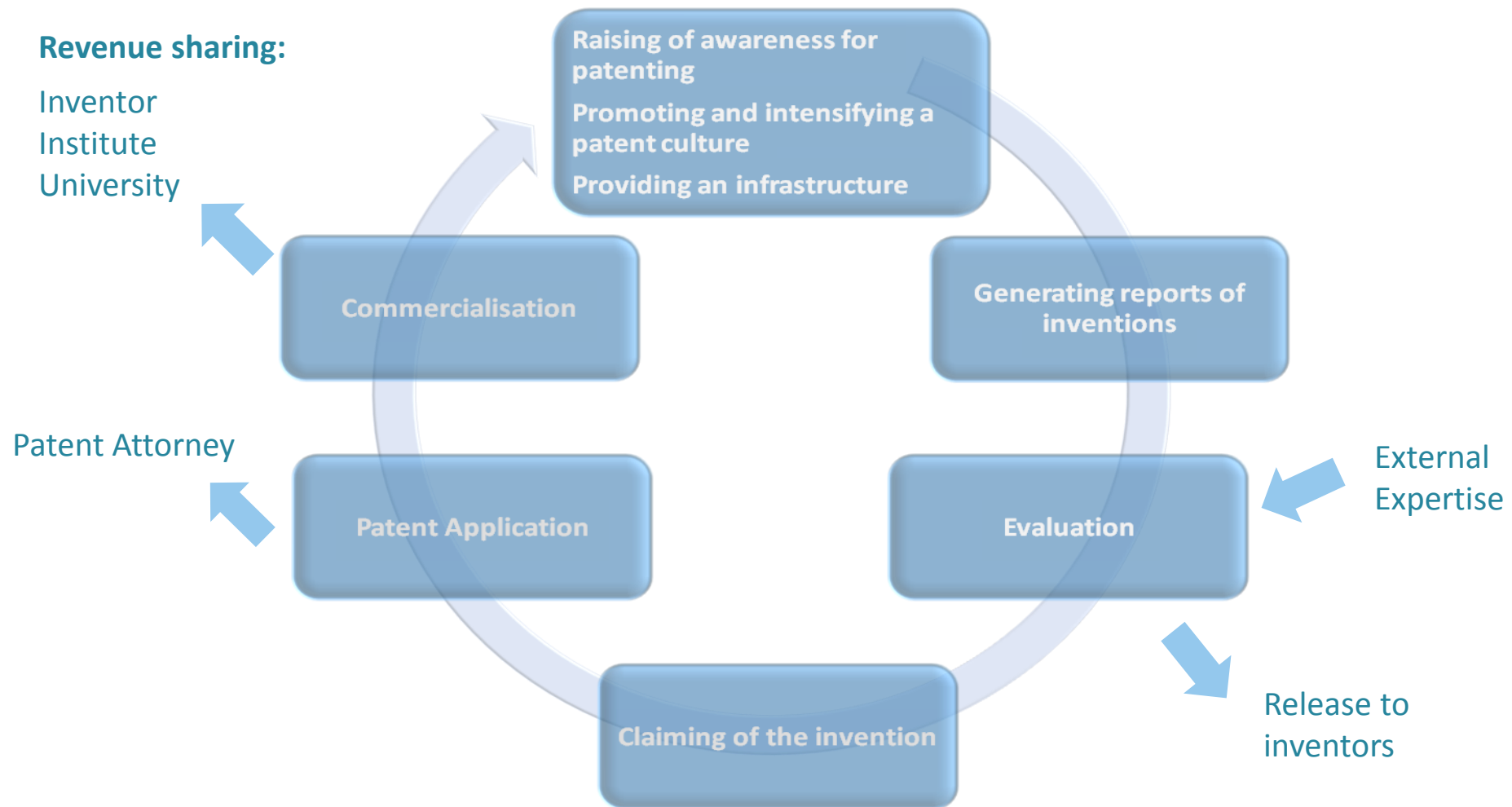
in close collaboration with:

- the TUM Central Administration (e.g. The TUM Legal Office)
- other TUM entities (e.g. TUM Graduate School, TUM Integrated Research Centres)
- incubators, commercialization agencies, consultants, patent attorneys, funding institutions

TUM Patents & Licenses

- **Assistance** for inventors at TUM in protecting and commercializing their ideas
- **Consulting** on all issues related to the patenting process and to the commercial exploitation of research results
- **Identification** of patentable research results
- **Information sessions** on patenting and commercialization of research results
- Management of the **TUM patent portfolio**
- Management of the **commercialization revenues**
- **Cooperation with the TUM Legal Office** on IP issues concerning collaboration with academia and industry

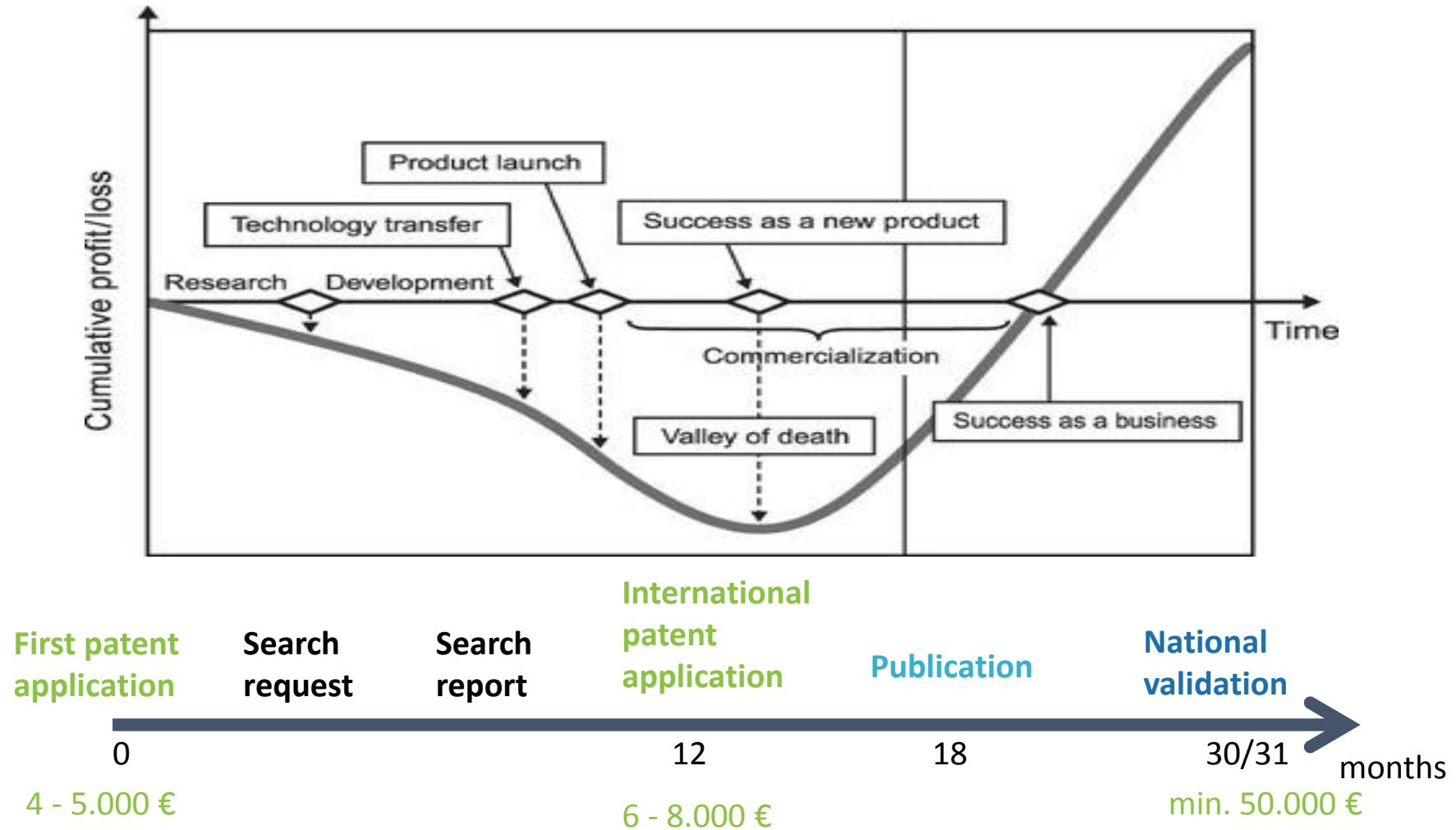
Life cycle of an invention in academia



Patent strategy in academia

- reasons for patenting a university invention: **commercialization** (95 %), **strategic considerations** (5 %)
- when you want to patent an invention, **it is all about its economic potential**: will the user of the patent have a benefit from using it?
- it doesn't count if your invention is **excellent science** or how much **time and money** you have already invested
- to figure out the **economic value is the most difficult part** in the valuation of inventions
- **prognosis** is very difficult because they are often **immature**
- the most common reason for a Technology Transfer Office to reject and release an invention is that **the expected revenues will never cover the patent protection costs**

Patent strategy: the right point in time



From: Osawa & Miyasaki, 2006, *An empirical analysis of the valley of death*

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Commercial exploitation of IPR

- **licensing** of IPR to companies: IPR remains at the university
- **sale and assignment** of IPR to companies: IPR is assigned to the company
- **provision** of IPR to university spin-off or start-up companies in form of:
 - **exclusive licensing**: IPR remains with the university
 - **sale and assignment** of IPR (IPR is assigned to the company)
 - **sale or exclusive licensing** of IPR → university obtains equity in return
- further development of the technology as part of a **cooperation**

The **choice of strategy** depends

- on the technology
- the market
- the interest of the inventors in a spin-off foundation

Licensing

- Licensing is still the preferred way to commercial exploitation of IPR, materials and know-how.
- The licensing of a patent is preferable than its sale because the owner reserves the greatest possible control over the patent and the related technology:
 - The Licensee can be imposed with an exercise duty and even the License Agreement may be terminated if the Licensee fails to fulfill its duties.
 - It is also possible to license out (non-exclusive) to several partners and to bring the technology widely in the market.

Licensing Strategy

Things to be considered

- technology and its uniqueness
- stage of development
- position in technology life-cycle
- presence/absence of competition
- technical, financial and marketing strengths of the parties
- strength of protection (via patent or other IPR)
- freedom for the licensee to practice the technology (FTO)
- compensation expected to be realized over the term of the license (type of payments)
- inventors and their contribution (current and future)

Types of licenses

- **Non-exclusive license:** it gives several Licensees as well as the Licensor the right to develop products utilizing the IP.
- **Exclusive license:** one Licensee receives exclusive rights to develop technology or products utilizing the IP. This means that both the licensor and other potential licensees are disclaimed from exploiting the IP.
- **Options** will give to the potential licensee the option - based on a fee- to negotiate a license within a specific time, while the company evaluates the commercial potential of the new technology.

Methods for estimating the value of a technology

- "Rule of thumb" -only with a lot of experience!
- Patent auctions
- Bench Marking: what is the value of similar technologies? Are there similar deals?
- Review: how much money has been expended to move to the invention, or produce a material?
- Determination of Net Present Value (NPV): All in advance-estimated risks, costs and revenues, which arise in the development, marketing and sales of the technology, are estimated and netted.

Commercialization partner – licensee

How do I find the right licensee?

- Often personal contacts of the inventor ensure that a potential licensee is just around the corner.
- Alternatively, potential licensees can be identified by search.
- Very good sources include:
 - Web Search Engines
 - Thompson Reuters Reports
 - Patent databases
 - Nerac database

Commercialization partner – licensee

How do I find the right person?

- After creating a list of potentially interested companies appropriate correspondents are identified which will evaluate a technology offer or forward it to the right people in the company.
- Usually such people are working with the Licensing Team of the Business Development department.
- Appropriate contacts for sending in a technology offer may be identified on the web pages of the company and contacted by phone or email.
- Often such contacts lead to a “wish list“, in which a company discloses relevant interests to them.

Documents and agreements in the licensing process

- Technology Offer
- Non-Disclosure Agreement
- Material Transfer Agreement
- Term Sheet
- Licence Agreement

Magnetic Stimulation System with Random Pulse Generation

Reference Number

B69200

Background

Magnetic stimulation is a well-known noninvasive neurostimulation technique that evokes action potentials in nerves via electromagnetic induction. This technique was originally developed for stimulating neurons noninvasively in the brains of conscious subjects. However, several advantages of magnetic stimulation over its electrical counterpart have transformed this method into a competitive method for a number of other applications like sports medicine and neurorehabilitation.

In addition to coil design, the pulse dynamics, i.e., the shape of the pulse determine the effect. In transcranial magnetic stimulation (TMS), this most notably concerns stimulation selectivity and neuromodulation. However, so far technological issues have obstructed the generation of different waveforms.

In contrast to the spatial characteristics of the induced electric field, which can be addressed relatively easily by appropriate coil design, the generation of different waveforms and the exploration of neuron dynamics has been obstructed by either limitations of high-voltage semiconductors or cost.

Innovation

The invention describes the first pulse source technology that is able to generate different kinds of pulse forms like:

- harmonic (monophasic, biphasic, polyphasic, etc.)
- nonharmonic (rectangular)
- nonperiodic
- repetitive monophasic

The possibility to generate user-programmable pulse forms within a pulse sequence would have advantages like:

- The stimulation pulse can be optimised¹ to stimulate only a certain group of neurons while other neuronal cells in the neighbourhood remain practically unaffected.
- Pulses can be optimised to practitioners needs, like reduced power consumption or less clicking noise e.g. to use magnetic stimulation in sleep research.

Origin

Technische Universität München

Industrial Sector

Medical technology & devices

Keywords

Magnetic stimulation, reduced power consumption, rehabilitation, neurology

Patent Situation

EP (07/2012) pending
US (07/2012) pending

Offer

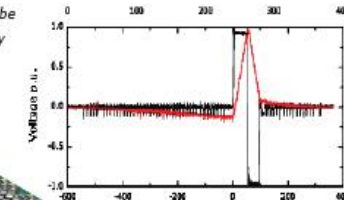
Cooperation, license, option, purchase, world-wide, exclusive

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Current and voltage can be controlled very accurately



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Commercial Opportunities

The invention enables the construction of magnetic stimulation systems that are no longer constrained to sine-wave pulse forms. The whole circuitry can be produced at much lower cost compared to existing technologies. With an optimised pulse form the uptimes of the system can be prolonged (less over heating), resulting in a more effective treatment of the patient. This invention offers the possibility to replace electrical stimulation by painless magnetic stimulation.

Developmental Status

The team has built a first prototype (see picture) of the design and successfully provided a proof of concept. A second generation is currently in development.

¹ Goetz SM, Truong CN, Gerhofer MG, Peterchev AV, Herzog H-G, et al. (2013) Analysis and Optimization of Pulse Dynamics for Magnetic Stimulation. PLoS ONE 8(3): e55771. doi:10.1371/journal.pone.0055771

Glypican-3-specific T-cell receptor and its uses for immunotherapy of hepatocellular carcinoma



Adoptive T-cell therapy of hepatocellular carcinoma

Reference Number

B74044

Background

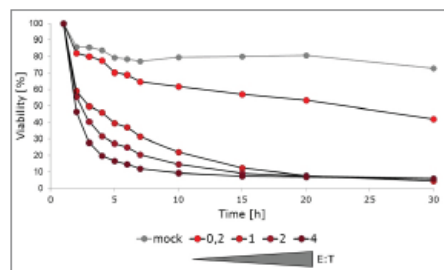
Hepatocellular carcinoma (HCC) is the most common primary liver cancer and the third most common cause of cancer related death worldwide. Less than 40% of all patients fulfill the criteria for curative treatment like tumor resection or liver transplantation. Furthermore, the risk of tumor recurrence is high. Patients with advanced HCC can only undergo palliative treatment such as local ablation or the multikinase inhibitor sorafenib. As a result, the prognosis of HCC remains poor and new therapies are urgently needed.

Innovation

Adoptive T-cell therapies led to significant improvements in cancer therapy in the last years. The Science Magazine even awarded this technology as "Breakthrough of the year 2013". However, for HCC patients, an immunotherapeutic strategy does not exist at the moment, although other methods of treatment are almost ineffective and T-cell infiltration in HCC is associated with better outcome.

The tumor-associated antigen Glypican-3 is not expressed in healthy human liver, but reactivated in up to 70% to 80% of all HCCs and therefore highly suitable for an immunotherapeutic approach. The discovery of so far unknown immunodominant Glypican-3-epitopes and the according T-cell-receptor now enable an adoptive T-cell therapy for HCC patients.

Figure: Killing of GPC3+ human hepatoma cells by T-cells engrafted with the GPC3-specific TCR P1-1. GPC3+ HLA-A2+ HepG2 cells were incubated with P1-1 transduced T-cells at



different effector target (E:T) ratios and target cell viability was measured over time. P1-1 enables T cells to rapidly kill target cells at low E:T ratios.

Origin

Technische Universität München

Industrial Sectors

Pharmaceutics & medicine

Key Words

Hepatocellular Carcinoma, T-cell receptor, T-cell therapy, Glypican-3

Patent Status

EP [05/2014]

Offer

Cooperation, license, option, purchase, world-wide, exclusive

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Commercial Opportunities

The incidence of HCC worldwide is rising steadily because of the prevalence of hepatitis B and C virus infection and other causes of hepatic cirrhosis, as for example alcohol abuse and metabolic liver disease. The outcome is poor, as only 10-20% of hepatocellular carcinomas can be removed by surgery. If the cancer is non-resectable or in the relatively frequent event of secondary tumors, treatment options are very limited and the disease outcome is fatal within 3 to 6 months. Therefore, the large majority of HCC patients represent a significant unmet medical need for more effective therapy options.

The present invention offers new opportunities for the detection, diagnosis, prognosis, prevention and/or treatment of liver cancer, in particular hepatocellular carcinoma (HCC), or other cancers expressing GPC3.

Possible applications of the invention would be:

- Adoptive T-cell therapy
- Use of a bi-specific antibody or bi-specific T-cell engager (BiTE)
- Use of soluble or chimeric TCR constructs
- Development of a peptide-based vaccine

Developmental Status

- Proof-of-concept *in vitro*
- *In vivo* experiments in preparation

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Non-Disclosure Agreement

- Recitals

The Parties intend to collaborate in the field of [...].

Prior to the commencement of the collaboration it may be necessary for the Parties to exchange certain proprietary information that should be kept confidential to protect the Parties' rights.

A Party disclosing confidential information reserves the right to file applications for intellectual property protection of such confidential information.

- **Disclosure of information:** in writing, orally, or in any other way, for the purpose set out in the Recitals or of which the Parties otherwise became aware of

Non-Disclosure Agreement

The Parties undertake to

- to treat the Information as **confidential**;
- not to use the Information except for the purpose stated above and, in particular, **neither to publish it, apply for intellectual property protection therefor nor use it commercially**;
- **not to disclose** the Information nor make it otherwise available to third parties; third parties shall include affiliated companies, licensees, or clients;
- to take all steps necessary to **prevent unauthorized access** to this Information;
- to give access to this Information only to employees whose **work is related to the purpose** set forth in the Recitals and who are **obliged to observe the confidentiality requirements** hereunder
- The Parties shall ensure that this **shall also apply if such employees leave University or Company** during the term of the Agreement and certain period after termination.

Term Sheet

- The Term Sheet specifies **key points** of a forecasted transaction , even if the motives and intentions of the contractors can later still strongly differ.
- Most of the provisions in a Term Sheet are **not legally binding** , but the **psychological impact** of such a document makes the renegotiation of substantial changes difficult.
- It thus depends on the **determination** of important concerns and **flexibility** on minor points.
- For the negotiating team it is critical to avoid typical pitfalls and to have **strategies** on hand to counteract undesirable developments .

Term Sheet

When do you need a Lol, a MoU or a TS?

preliminary discussions



contract negotiations



signing of contract

**Letter of Intent,
Memorandum of
Understanding**

Term Sheet

Contract

Letter of Intent
and confirmation of
interest in
negotiations

Description of
substantially
cornerstones of planned
collaboration

Implementation of
Term
Sheet and the
negotiation results

Licence Agreement

Requirement for a license agreement

- IP right: patent, utility model, trademark, etc.
- License: Contractual permission to use an IP right (according to the contract) of a third party that is not general available

Nature / legal nature of a license agreement

- Positive permission right or right of use
- Negative veto rights
- Partially absolute or real right
- Mandatory rights

Economic risk of a license agreement

- The licensee bears the risk of the commercialization
- Except reasonableness border to "good faith"
 - (+) When "more or less" economic crap materials must be produced
 - (+) If the economic exploitation (agreement) is eliminated

Types of license agreements

- **Patent License Agreement**
Patent or patent application
- **Know-how license agreement**
No legislation
Includes not general accessible technical or business management knowledge
- **Combined patent know-how license agreement**
Most frequently
- **Other license agreements**
e.g. for trademarks, etc.

Types of license agreements

Single and exclusive license

Exclusive

- Decision on the licensee very important and significant
- Licensee is for a certain period, region, type the **sole licensee**
- **No other licensees**
- Restriction in case of doubt also for the licensor
- Sometimes entry in the patent register
- Self-assertion of rights and obligations by the licensee
- The position of the licensee as right holder

Single license

- Licensor can issue as many licenses for the IP right
- Licensor may have complete freedom on the IP right
- Usually only mandatory (law of obligations) rights against the licensor as the contractor

Types of licensing fees

- Fixed license fee

As entry fee, cash advance, privileges, option fee, etc.

Simplest settlement, since no effort

- Sales license fee

Revenue per piece (item license)

Sales in% of the sales price (value license)

% Share of income (profit license)

Types of licensing fees

Sales license fee

- Usual remuneration model in combination with a Fixed License Fee with an emphasis on the variable part
- Height should be "adequate", that is what would arrange reasonable Partner
 - Pharma: 2-20%
 - ICT: 3- 8%
 - Engineering: 3-10%

Benefits for Licensee:

- No fixed load
- Economic risks may indirectly shifted slightly to the licensor

Contract negotiation and contract design

Checklist for contract negotiations and the draft contract:

- Do your homework, i.e. prepare well
 - What I want and why
 - What I do not want and why
- What IP rights does my partner have
- What things should I want to enforce strictly
- On what points I can do without
- Create friendly atmosphere
- If possible, no negotiation in foreign areas

Contract negotiation and contract design

Checklist for contract negotiations and the draft contract:

- Pragmatic solutions
- Deliver the first draft contract
- Beware of traps
- Simple formulations
- Alternatives / compromises in advance
- "Four-eyes principle"
- Contract maintenance or contract changes should be made to you
- No negotiations when outnumbered
- No overconfidence
- Keep the ball rolling, faster completion

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Do you know that you have the right and title to license?

- Expectation that you will warrant that you have **the right to license the IPRs** to exploit the technology
- Rights other than patent rights e.g. copyright, design rights
- Do the **contracts of employment** cover the particular facts for the patent rights?
 - Covers all research or just in a particular subject area?
 - Are all of the inventors employees of the University?
 - Are licences from third parties required?
 - What about background/sideground IP?

Do you understand the context in which you are licensing?

Not usually a straight license but commonly includes some **development work**

- A straight licence is to an identified registered IPR
- Often licensing a technology still **under research** (no specific end product already identified)
- The licensing may be simply the mechanism behind the contractual arrangement to **fund research**
- **Restrictions on future research work** of the team involved (exclusive and non-exclusive licensing, breadth of technology licensed and group of individuals involved)
- * The tension with the **need to publish** (applying reasonable timescales)
- * The **cost, time and risk to market** (sharing of cost and risk, ability to take rights back in a territory if not adequately exploited)

Do you know the technology?

Real need to **understand** and be able to **define** what you are licensing

- What falls within and without
 - and all derivatives thereof - is that all salts and esters?
 - ... a recombinant form of protein X - does whole sequence have to be present?
 - ... compounds in class X for use in ... - what if you find an alternative use?

What about improvements?

- What are they?
 - separable
 - inseparable
- Who creates them and who benefits from them?
- Potential loss of ability to re-license
- Competition law issues

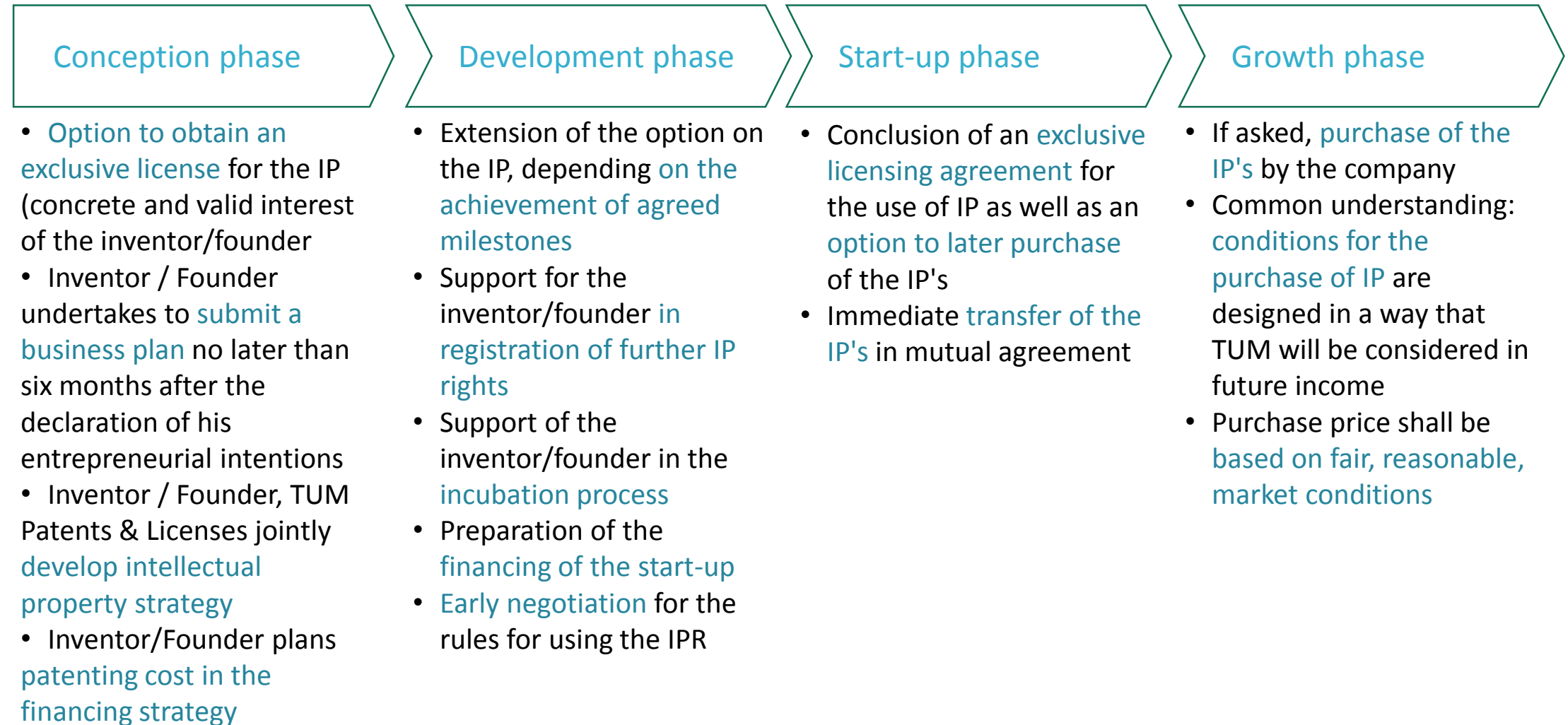
What about liabilities - initial and continuing?

- * Prosecution and opposition costs
- * Renewal fees
- * Enforcement and putting the validity of the rights in jeopardy
- * Warranties and indemnities
- * Payments made during application phase
- * Remuneration of inventors

Agenda

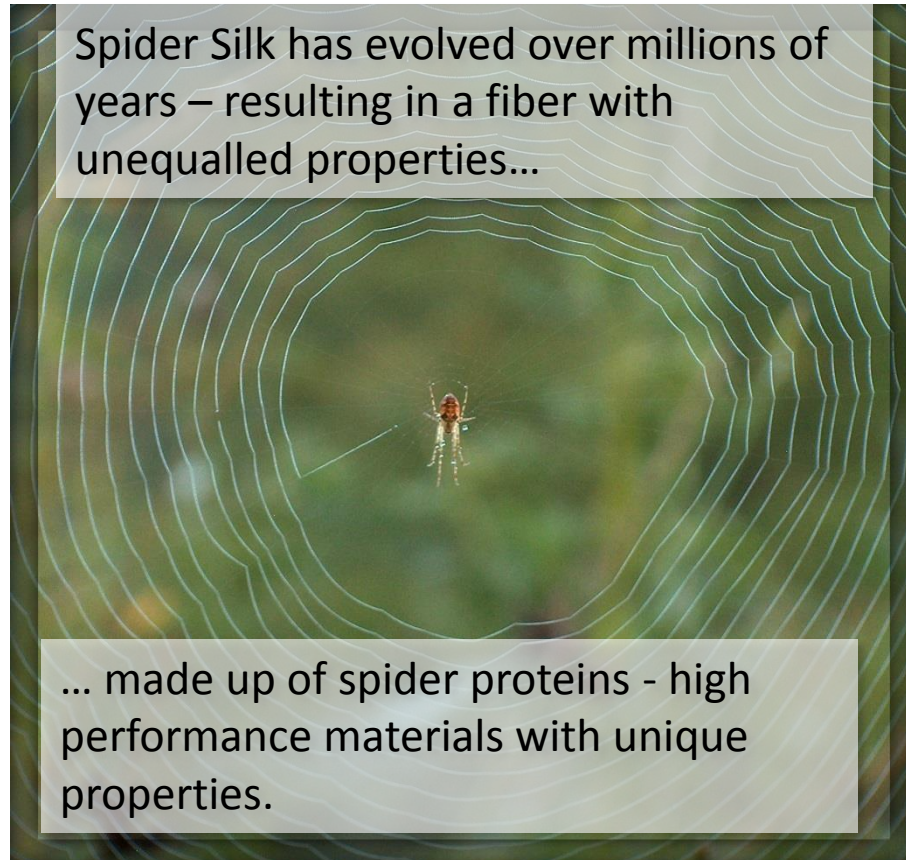
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TUM road map for dealing with IPR for start-ups



Case study: IPR and setting up a start-up

a fascinating material: **spider silk**



- High toughness
- High ductility
- Low density
- Monodisperse polymer
- Hypoallergenic
- Well-tolerated
- Breathable
- Modifiable
- Transparent
- UV-resistant
- Biodegradable
- Sustainable

Case study: IPR and setting up a start-up

Invention: synthesis of spider silk proteins by bacteria

New Materials for Industrial Applications

Based on Tailor-made Performance Proteins
Cleantech Biopolymers for High-Tech Products



Silkbeads

Particles for
Medical Technology
and Industrial
Applications



Nonwoven

Nonwoven for
Medical Technology
and Industrial
Applications



Films & Coatings

Modifiable Films
and Coatings
made of silk



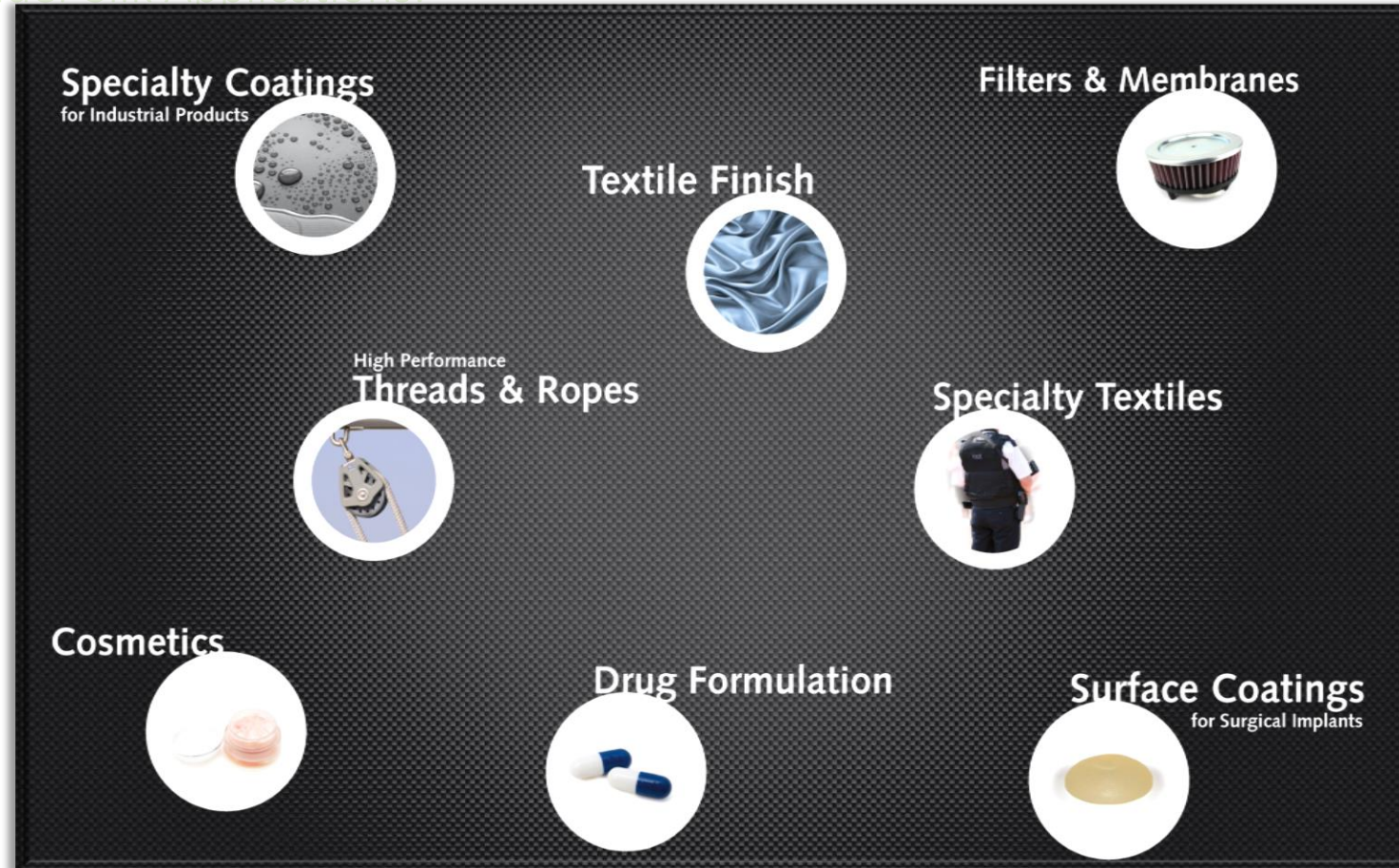
Fibers

High
Performance
Fibers and
Monofilaments

(L1) Version 100927

Case study: IPR and setting up a start-up

Spider Silk Applications:



Case study: IPR and setting up a start-up

- from the very beginning thoughts about the **commercialisation strategy**
- because of the enormous possibilities of the (growing) patent portfolio:
 - **no “one stop shop” solution**
- luckily a lot of possible applications = **a lot of markets**
- **high-tech portfolio**, which might come too early for the market?
 - “attractive technology is looking for feasible business model for the purpose of building the future together“
- **commercial applications** have to be developed
- negotiating with **many different commercialisation partners** would take too long

Case study: IPR and setting up a start-up

only reasonable commercialisation route for TUM: choose the (uncertain but exciting) way of setting up a company together with the main inventor and its team with the purpose of attracting investors and developing the technology for the different markets



Case study: IPR and setting up start-up

AMSilk GmbH company outline

- Incorporated in 2008; in Planegg (near Munich) Germany
- Management: two of the co-founders with business and scientific background, main inventor in the Advisory Board
- Shareholders: AT Newtec GmbH, MIG Fonds AG, [TUM](#)
- Close cooperations with several leading universities and companies world-wide
- Industrial scale production through leading service providers
- Extensive patent portfolio and several licenses
- Functional silk polypeptides - inspired by nature

Case study: IPR and setting up start-up

- AMSilk is worldwide the first manufacturer of silk-inspired biopolymers made by a biotechnological process
- AMSilk provides high-quality recombinant silk protein for cosmetics, medical devices and textiles.
 - Fibers & Finishing
 - AMSilk is the first producer of nature based SPIDERSILK Fibers in a continuous spinning process: BIOSTEEL FIBER
 - MedTech & Aesthetics
 - Silk enhanced medical devices with superior properties A BIOSHIELD for your product
 - Cosmetic Ingredients

Case study: the Anticalins[®] technology

- ▣ Anticalins[®] are **engineered ligand-binding proteins** with **antibody-like functions**
- ▣ **therapeutic use** in a variety of diseases, particularly in cancer and cardiovascular diseases
- ▣ technology invented in a large part at the TUM and developed at PIERIS Proteolab AG
- ▣ PIERIS was founded in January 2001 – after being awarded the first prize in the Munich Business Plan Contest 2000
- ▣ laboratories and offices are located at Freising-Weihenstephan, well situated in the neighbourhood of the TUM life science campus

see also:
www.pieris.com

Case study: the Anticalins[®] technology

“In July 2003, Pieris formed a **strategic alliance** with the Technische Universität München in order to **broaden the company's technology base and secure further developments** in the basic understanding of lipocalins and Anticalins[®].

Any **patent rights** arising are assigned to Pieris and the company has the exclusive right to in-license future inventions in the area of lipocalins and Anticalins[®].”

Press Release on the web site of Pieris AG, www.pieris.biz

Case study: the Anticalins[®] technology

- Intellectual Property Rights
 - (a) Company Inventions: are exclusively made by employees of the company
 - (b) Joint Inventions: are made by employees of the company as well by employees of the University
 - (c) University Inventions: are exclusively made by employees of the University
- Licensing Fees

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Sat, Apr 2, 2016, 9:54AM EDT - US Markets are closed

PIRS: Attains Favorable Ruling in Arbitration with TUM; Continued Positive Developments from Collaborations

Zacks/SCR By Zacks Small Cap Research
December 2, 2015 12:05 PM



By [David Bautz, PhD](#)

NASDAQ:PIRS

On November 25, 2015, Pieris Pharmaceuticals, Inc. ([PIRS](#)) filed an [8-K](#) describing the outcome of a confidential arbitration regarding the company's contract dispute with the Technische Universität München (TUM) under the Research and License Agreement by and between Pieris and TUM that was originally entered into in 2003 and amended and superseded in 2007.

The purpose of the arbitration hearings, which were initiated by Pieris, was to address issues re-

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Case study: the Anticalins[®] technology

“The purpose of the arbitration hearings, which were initiated by Pieris, was to address issues regarding the calculation of payments due from Pieris to TUM under the Research and Licensing Agreement. These payments due were the result of Pieris’ out-licensing revenues attributable to intellectual property covered by the Research and Licensing Agreement from 2004 to 2012. TUM had asserted that the out-license fee due from Pieris was €2,529,400 plus interest, while Pieris had calculated the out-license fee owed as approximately €0.4 million.

The German Institute of Arbitration ruled that the amount of out-licensing fees due for the disputed period is €859,854 and that TUM must reimburse Pieris €110,000 for fees incurred and dismissed TUM’s claim for reimbursement of its costs. After factoring in account interest payable on the out-license fee of €167,234, along with certain credits and the award of Pieris’ fees, the total amount payable by Pieris to TUM is approximately €917,088.

We do not anticipate this having a material impact on the company’s cash runway, and most importantly of all Pieris retains full exclusivity to the patents under the TUM Research and License Agreement, which covers certain intellectual property and know-how covering the Anticalin[®] technology.”

from Yahoo Finance

Thank you for listening!

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Agenda

- General introduction in commercial exploitation of IPR in academia
- Commercialization process
- Typical pitfalls in the commercialization of university inventions
- Case studies
 - Licensing to established companies or to spin-offs?
 - Licensing and collaboration
- Q&A Session