Innovation management in practice

How to create (commercial) value from university research? – Part 2

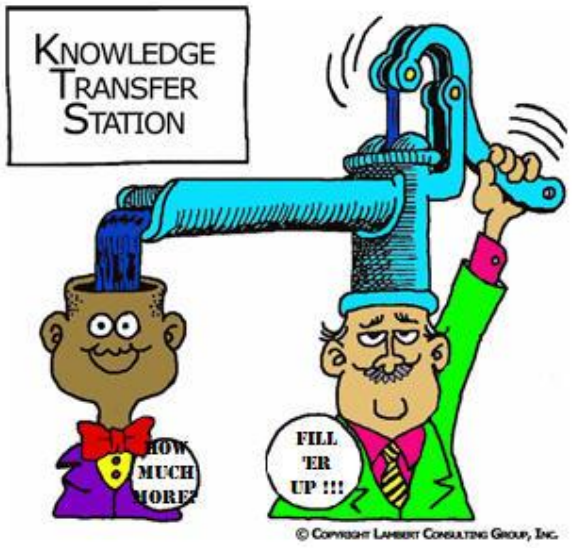
Tamás Bene
Head, Center for Research Commercialization and Technology Transfer
University of Debrecen

13th March, 2020

UD TECH TRANSFER

What is technology transfer?

Technology transfer is the **process of transferring** skill, knowledge, technologies, methods of manufacturing, samples of manufacturing and facilities **among public institutions and business entrepreneurs** to ensure that scientific and technological developments are **accessible** to a **wider range of users** who can then further develop and exploit the technology into new products, processes, applications, materials or services.



UD TECH TRANSFER

Knowledge transfer routes

1. Creation of knowledge

Research

2. Dissemination of knowledge

- Teaching, education
- Scientific dissemination (publication, conferences)
- Academic fellowship
- Collaborative research, contract research, private consultancy
- Licensing
- Establishment of spin-off companies
- Establishment of joint R&D companies with industrial partners
- Faculty and student entrepreneurship (outside the university)
- Movement of highly skilled research staff to industry

Intellectual Property commercialization

1. Research agreement
2. License/assignment
3. Spin-off/start up company

UD TECH TRANSFER

Essential goals of university technology transfer activity

- Getting results from public research **beneficial to the society**.
- Transfer research results to **industry**.
- **Improve funding opportunities** for the university and the researchers.
- Provide framework to the institution and the researchers for **carrying out research** with third parties.
- Generate **income** to the university and the researchers.

The Technology Transfer Office (TTO)

General tasks of the technology transfer office:

- **Dissemination** of research capabilities of the university
- Build **partnership** with research partners and enterprises
- **IP management**
- **Licensing**, spin-off and start-up support
- Taking part in **business negotiations** and drafting **agreements**
- **Training** of the faculty and students
- Support of the development of the **local economy**

Who do they serve?

- Management
- Researchers
- External partners
- Students
- Citizens

UD TECH TRANSFER

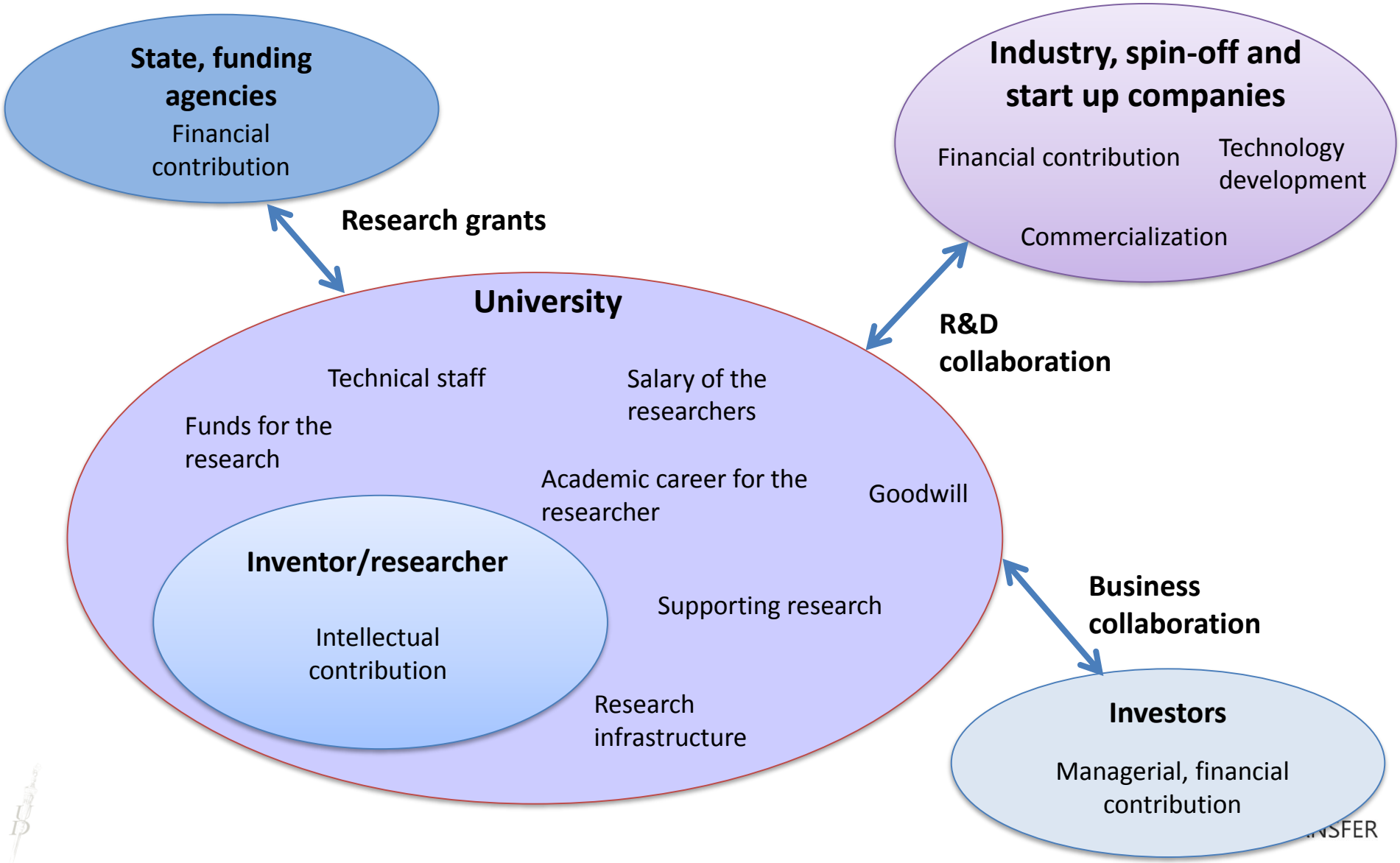
Practical guidelines for researchers in IP management

IP policy

An IP Policy relates to the ownership, protection and commercial exploitation of intellectual property created by researchers in the course of their duties or activities at the given Institute. It sets out the rules of the Institute for **cooperation with industrial and business organizations** and provides **guidelines on the sharing of the economic benefits** arising from the commercialization of intellectual property.

- **Personal scope**
- **Types of IP covered**
- **Ownership of intellectual property**
- **Research management, including rules for contracts, confidentiality, public disclosure, and conflict of interest**
- **Obligations and deadlines for IP management**
- **Distribution of revenues, motivation of scientists**

IP ownership is always a fundamental aspect



Inventorship

- **Inventorship is the basis of ownership of inventions**
- Therefore it is essential to identify the true inventor(s)
- Inventorship is legally determined

‘The formation, in the mind the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice’

1. Conception
2. Reduction to practice

By itself conception isn’t considered an invention.

Joint inventorship

- Inventorship may be joint inventorship
- It is the **contribution to the conception** that counts
- Merely following the instructions of another and performing experiments to implement the invention is not sufficient to be classed as an inventor
- This is an important issue for supervisors and students

Would the invention have occurred without the contribution?

Proving inventorship

- Claim of inventorship has to be verified
- Inventorship is a **matter of law,** not policy or academic title
- The validity of a patent can be challenged on the basis of incorrectly nominated inventor

Even years after the research work, you must be able to prove to the satisfaction of a court:

- WHAT work was done
- WHO did the work
- WHEN was it done
- Nothing has been added or deleted subsequently.

Record keeping

Use a proper paper-based or electronic lab book to record hypotheses, experimental design and objectives, results, failures, calculations, print outs, photographs.

Basic rules for paper books:

- hard bound books, numbered sequentially
- written in permanent ink not pencil, no erasures or white-out, no blank spaces, in chronological order, with an index
- pages numbered sequentially, dated, signed and witnessed by someone with an understanding of the work
- stored securely for the long term.

Role of the TTO in the IP management process

- Receiving invention disclosures, technology scouting
- Preparing opinions on patentability
- Evaluation of the commercial potential of the invention (or other IP)
- Obtaining patent protection, managing the patent prosecution process
- Finding industrial partners, raising venture capital, negotiation of license agreements
- Follow-up of the commercialization process
- Distribute revenues between university and inventors
- Negotiation of research and collaboration agreements

Identification and disclosure of IP

Invention disclosure – Why do you have to disclose your invention?

Generally all rights in Intellectual Property created by **researchers** in the course of their duties and activities of employment **belongs automatically** to the employer (university or research institute or the state).

If a **student** creates Intellectual Property with the significant use of Institute Resources in connection with his or her research activity, he or she might transfer the IP Rights in such intellectual property to the Institute as consideration for the use of Institute Resources.

Generally universities claim ownership of all Intellectual Property created in the course of **postgraduate (doctorate) students'** research activity.

Identification and disclosure of IP

The invention disclosure allows the University to determine whether it wishes to retain the ownership and control to pursue commercialization or to release the innovation back to the inventor.

When to disclose?

- As soon as you become aware of the commercial potential of the IP.
- Before publishing or disclosing the information to third party.
- If you are in doubt whether your innovation is commercially exploitable.

How to disclose?

The best way to do it through **invention disclosure forms**.

Where to address the invention disclosure?

To the technology transfer office or other equivalent department dealing with innovations.

Expected information on an invention disclosure

- Name and department of all innovators who have made **creative contributions** to the innovation
- **Dates** of research work and reduction to practice
- A statement detailing **how the innovation works** and how it is used
- A **description** of the innovation, along with a **comparison** to other potentially similar technologies and practices
- A summary of the **development status** of the innovation, including data obtained to support and verify its functionality (proof-of-concept)
- Future steps for **further development**
- A list of **third party partners** who collaborated in the research work or who provided funding
- Potential **commercial** partners
- A detailed description of any known **prior art** and its disadvantages or shortcomings

It is important to keep records of the events leading up to one's invention (e.g., laboratory notebooks), as such materials can become important in establishing: the true inventor(s) of an invention and the dates that conception and/or reduction to practice took place.

Publishing vs. patenting

These options are not mutually exclusive!

You can publish and patent without losing any patent rights.

Filing the priority patent application must precede any public disclosure.

However, the decision to pursue patent protection is largely a business decision, while the decision to publish is a scientific one.

How to avoid public disclosure before obtaining IP protection?

Early disclosure may compromise the protection and commercialization of Intellectual Property.

Examples for public disclosure:

- *Publishing anything - e.g. an abstract or scientific journal article*
- *Giving a talk or poster presentation at an "open" meeting outside the University*
- *Talking with external parties about the innovation (without having a Confidential Disclosure Agreement in place)*
- *Transferring scientific materials (without the use of a Material Transfer Agreement)*
- *Submitting grant progress reports, which are accessible to the public*
- *Posting or publishing a student thesis (under some circumstances), even if nobody ever actually reads it*
- *Conducting classroom presentations, including distributing handouts*
- *Presenting at department seminars*

Always consider the consequent impacts of any public disclosure!

How to avoid public disclosure before obtaining IP protection?

Activities which may be performed without jeopardizing the patenting:

- *Lab and faculty meetings attended by University employees only*
- *Confidential submissions for publications. These remain confidential prior to acceptance by publishers.*
- *Generally the submission of project proposals for grant applications (however it is advised to review the rules of submission).*

Confidentiality agreement

In a non-disclosure agreement two parties agree that they will not disclose each other's confidential information. In general, confidential information is defined as the information, owned by a party, which is not publicly accessible.

Material Transfer Agreement (MTA)

An MTA regulates on the exchange of research materials between laboratories. These agreements stipulate:

- who is liable when material is misused or damaged;
- which party will own the rights to the results obtained by the use of the material and/or which party will have the rights to commercially use such results.

Decision on whether to invest in the intellectual property

Launching protection and exploitation is basically a **business decision**, therefor proper scientific and economical **evaluation** is critical.

As an inventor you have to give **reasonable assistance** in evaluating, protecting and commercially exploiting the Intellectual Property by providing information, attending meetings and advising on further development.

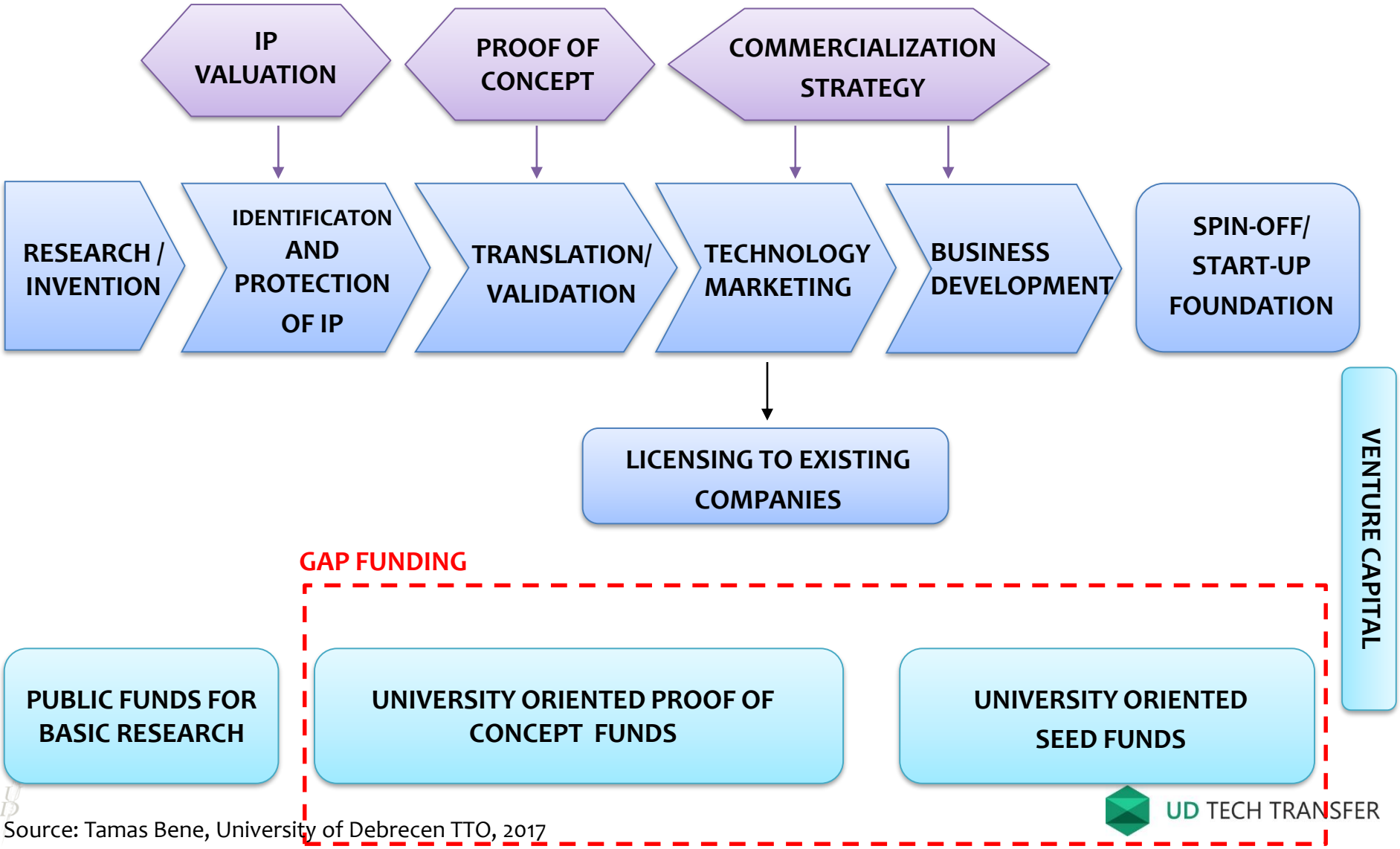
As a **result of the evaluation**, the university might:

A) Accept and approve the invention disclosure

B) Release it back to the inventors

C) Suggest to further develop (and refrain from publishing), e.g. to gain commercial value

University technology management



Source: Tamas Bene, University of Debrecen TTO, 2017

UD TECH TRANSFER

US patent: Method of exercising a cat

US005443036A

United States Patent [19]

Amiss et al.

[11] **Patent Number: 5,443,036**

[45] **Date of Patent: Aug. 22, 1995**

[54] **METHOD OF EXERCISING A CAT**

[76] Inventors: **Kevin T. Amiss**, 255 S. Pickett St., #301, Alexandria, Va. 22304; **Martin H. Abbott**, 10549 Assembly Dr., Fairfax, Va. 22030

[21] Appl. No.: **144,473**

[22] Filed: **Nov. 2, 1993**

[51] **Int. Cl.**[6] **A01K 29/00**

[52] **U.S. Cl.** **119/707**

[58] **Field of Search** 119/702, 707, 174, 905;

5,194,007 3/1993 Marshall et al. .

OTHER PUBLICATIONS

Carayan et al., "Effects of tianeptine on the Performance of a reaching movement in a cat", *Psychopharmacology*, vol. 104, Issue 3, Berlin, 1991, pp. 328–336.

Levesque et al., "Visual 'cortical–recipient' and tectal–recepient pontine zones play distinct roles in cat visuomotor performance", *Behavioral Brain Research*, vol. 39, Netherlands, 1990, pp. 157–166.

Primary Examiner—Todd E. Manahan

A method for inducing **cats to exercise** consists of directing a beam of invisible light produced **by a hand-held laser apparatus** onto the floor or wall or other opaque surface in the vicinity of the cat, then **moving the laser** so as to cause the bright pattern of light to move in an irregular way **fascinating to cats**, and to any other animal with a chase instinct.

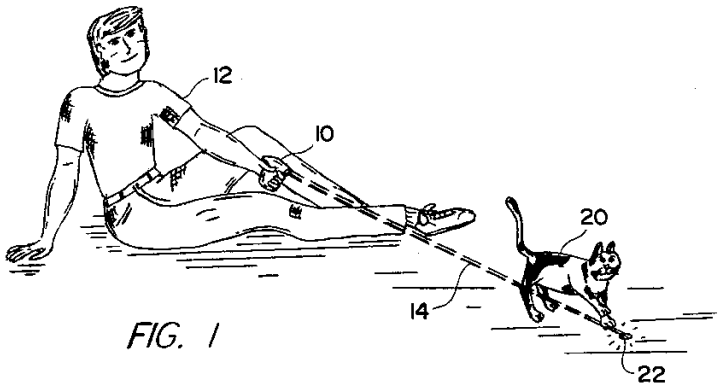


FIG. 1

Main aspects of IP evaluation at the TTO

- Is the technology patentable and could a patent be enforced?
- Is there a market for the invention?
- What is the stage of development?
- Is there a dedicated team to further develop the product/service?
- Can we find a business partner interested in licensing, developing and commercializing the technology?
- Can we start a new company?
- **Are there available resources to help further develop the inventive technology?**

Challenges in licensing efforts

What technologies are companies looking for?

- Unique, disruptive innovation
- Solution to an existing problem
- Have big market potential
- Have competitive advantage
- Strong IP protection
- Easy to acquire
- Advanced stage of development
- Easy to implement
- Competitors are excluded
- Probability of success is big
- High potential in the return of investment

Proof of Concept (PoC)

Activities

- Technical feasibility studies
- Prototyping
- Specialist testing and/or demonstration testing
- Market research, testing and competitor analysis
- IP protection and IP position assessment
- Investigation of production and assembly options

Stage of development

Technology readiness levels

- TRL 2 - Technology concept formulated
- TRL 3 – Experimental Proof of Concept
- TRL 4 – Technology validated in lab

Source: Review of UK Proof of Concept Support, 2015

University of Debrecen – Innovation Fund

New financial instrument to support innovative research and other third mission activities

Proof of Concept Fund

- First round closed in April, 2018
- Funding up to 30k EUR for 9 months
- Available for university research groups
- The technology must be registered within the TTO and the commercial potential must be clearly identified

UD TECH TRANSFER

Evaluating Commercial Potential Through Market Research

- Is there a clear product?
- Does it solve a significant problem?
- Will the customer pay for it?
- What is the market size?
- What are competitive products?
- Who are likely licensees?
- What are legal and regulatory barriers?

Understanding the market is critical!

Market Research Resources

- Proprietary Tools and Databases e.g. MedTrack, BCC Research, Frost&Sullivan, etc
- Industry contacts
- Expert analysis
- Outside market research firms as resource
- Publicly available resources e.g. Google, News Feeds, Blogs, Business Journals, Patent databases
- Inventor feedback

Market Research

- Pipeline analysis – target, indication, type, stage of development etc.
- Company – management, finance, recent news, competition
- Market factors – size, competitive technologies, regulatory requirements, funding environment
- Patent landscape, patent ownership analysis

Packaging and Selling Your Technology

Writing Effective Non-confidential Summaries

- Highlighting your technology: Include possible application
- Tailor it to the specific needs of your marketing target: How your tech may be enhancing the company's portfolio
- Why is yours better than the existing solutions: Competitive Advantages
- A Picture is worth a thousand words: Include key data figures
- IP and Publication Status

Drug Development: Time, Probability of Success, Cost, Value and Opportunity

Drug Development										
	Target Discovery	Screening & Hit Generation	Lead Generation	Lead Optimization	Preclinical Study	IND Enabling Studies	Phase I	Phase II	Phase III	FDA Approval and Market
Time (Yrs.)		1.0	1.5	2.0	1.0	1.0	1.5	2.5	2.5	1.5
Probability of Success		80% (24.3)	75% (19.4)	85% (14.6)	69% (12.4)	69% (12.4)	54% (8.6)	34% (4.6)	70% (1.6)	91% (1.1)
Cost ($M)		$1	$2.5	$10	$0.5	$5	$15	$40	$150	$40
Value	1x	2x	5x	10x	15x	20x	25x	50x	200x	nX
				Research Institutes, Angels, PoC Centers		VCs, Entrepreneurs & Small & Mid Cap Biopharma			Big Pharma & Biotech	

Opportunity Space

*Steven M. Paul et al,
Nature Reviews Drug Discovery 2010, 9, 203-214*

*This slide was kindly provided by Nirdesh K. Gupta, PhD, CLP
Tech Transfer Office, Cedars-Sinai Medical Center*

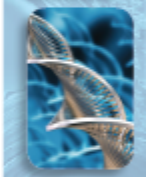
UD TECH TRANSFER

One-pagers

Methodology and bed-side kit for measuring the plasminogen activator activity in tear fluid to predict relevated risk for haze after photorefractive keratectomy

University of Debrecen

InnoTears Ltd., a spin-off company of the University of Debrecen, has developed a bed-side kit which can measure plasminogen activator activity in tear fluid to predict elevated risk for haze after photorefractive keratectomy. The University of Debrecen has acquired the owner rights of the patent application and now it is seeking for partners to utilize the invention.



Background

Some fraction of patients who have laser vision correction develop haze (cloudy vision) and may experience halos, glare and starbursts several months after the surgery: about 1% to 10% of both photorefractive keratectomy (PRK) patients and laser-assisted sub-epithelial keratectomy (LASEK) patients. Haze is a form of light scattering that occurs in the post-surgical wound healing region of the cornea.
At present there is no pre-surgical predictor for the potential formation of these visual aberrations, nor a preventative to eliminate the problem.

Both in rabbit and human eyes with normal wound healing, plasminogen activator activity (PAA) becomes elevated in tears above the preoperative level on the third postoperative day, and then returns to normal by the fifth postoperative day. In contrast, PAA activity remains low through the third postoperative day in all eyes in which haze developed after 3 to 6 months post-operatively. Thus the extended low levels of PAA through the third postoperative day correlate with the development of post-PRK haze.

Invention and technology

InnoTears Ltd, a spin-off of Debrecen University, has developed a bed-side kit which can measure PAA in the tear fluids in less then 30 minutes, thus can identify:

i) subjects who are at high risk during PRK, due to the low level of PAA
ii) subjects with elevated risk for developing haze after PRK due to the low level of PAA on days 3 to 5 postoperatively.

The kit uses a chromogenic substrate of plasmin in the presence of plasminogen, and the observed yellowness in the sample spot is proportional with PAA.

Commercial opportunity

Measurement of PAA in tear fluids and the provision of semi-quantitative data provide
a number of opportunities such as the ability to predict development of haze and to omit PRK in patients with low preoperative PAA level or to develop new eyedrops restoring normal PAA profile in the tears after PRK.

Next steps

A patent application has been filed over these findings and the University of Debrecen is now seeking partners to develop this invention.

Medical and Health Science Center

Knowledge & Technology Transfer Office

Contact: Prof. László Mátyus, Director of TTO • E-mail: gnd@dote.hu • Tel.: +36 30 229 5890

New types and uses of plastic – The titanate-polymer nanocomposits

University of Debrecen

Researchers at University of Debrecen in collaboration with researchers from University of Szeged have developed a new plastic family (approximately forty plastic nanacomposits) that can be created by the use of nanopipes and nanothreads. These new materials have more advantageous attributes than the everyday used conventional plastic composits.

Background

Production of polymer nanocomposits by the use of titanate nanopipes and nanothreads. The invention is based on the new revelation, that $H_2Ti_3O_7$ nanopipes and nanothreads produced by hydrothermal synthesis have amphiphilic attributes depending on the applied technology in the production. In this manner they can be joined with different apolar and polar polymer matrixes by a simple technological process, forming all-round utilizable nanocomposits.

Invention and technology

By applying this technology, a new plastic family can be produced. Approximately forty plastic nanocomposits were created by the use of nanopipes and nanothreads. These new materials have more advantageous attributes than the conventional plastic composits: they have better tensile strength and gas-tight.

The new plastics are appropriate for several clinical targets with adequately equable nanothreads and nanopipes: with their use the average life of a hip prosthesis can be significantly elongated. Biocompatible dental prosthesis and filling materials can be prepared as well.
These favorable plastics made from titanate-polymer nanocomposits can be used for gasfillers and underfloor heating.

Title of the patent application: Titanate-polymer nanocomposits and process for their production (P0700484; shared patent application with University of Szeged).

The patent application is under process.

Commercial opportunity

- More advantageous attributes than the conventional plastic composits
- Potential of all-round utilization
- Exploitation in medical field

Next steps

University of Debrecen is now seeking partners to license the technology or to discuss spin-off foundation.

Centre of Arts, Humanities and Sciences

Knowledge & Technology Transfer Office

Contact: Prof. László Mátyus, Director of TTO • E-mail: gnd@dote.hu • Tel.: +36 30 229 5890

UD TECH TRANSFER

Commercialization

1. **License strategy:** license the technology to an existing business.

2. **Spin-off strategy:** create a new company and contribute the technology to the spin-off in exchange for equity and royalty payments.

Commercialization is Teamwork

How inventors can help:

- Remain available and accessible
- Provide any potential leads
- Provide broad pointers for tech positioning e.g. market segment, application field etc.

TTOs responsibility:

- Research market segment or field to identify right prospects
- Prepare summaries and contact companies
- Follow ups, conf. calls, CDAs, licensing negotiations, post-licensing compliance etc.

This slide was kindly provided by Nirdesh K. Gupta, PhD, CLP
Tech Transfer Office, Cedars-Sinai Medical Center

License

Patent licensing agreements are contracts in which the patent owner (the licensor) agrees to grant the licensee the right to make, use, sell, and/or import the claimed invention, usually in return for a royalty or other compensation.

Financial terms can include:

- Upfront payment
- Annual minimum payments
- Earned royalties
- Equity (if appropriate)
- Reimbursement of patent costs

Non-financial terms can include:

- Field of Use
- Non-exclusive or exclusive rights
- Development milestones and diligence provisions

University spin-off entrepreneurship

Spin-off is a newly established company whose prior mission is to commercialize technologies or services created at the university.

Three types based on their main goal:

1. Commercialization of a technology via licensing or assignment.
2. Sponsoring university research to develop a technology, which will be licensed by the spin-off company at a later stage.
3. Providing service, which was originally provided by a department of the university.

Key factors for spin-off establishment:

- Secured IP protection
- Business plan
- Management (scientific and business)
- Availability of financial resources

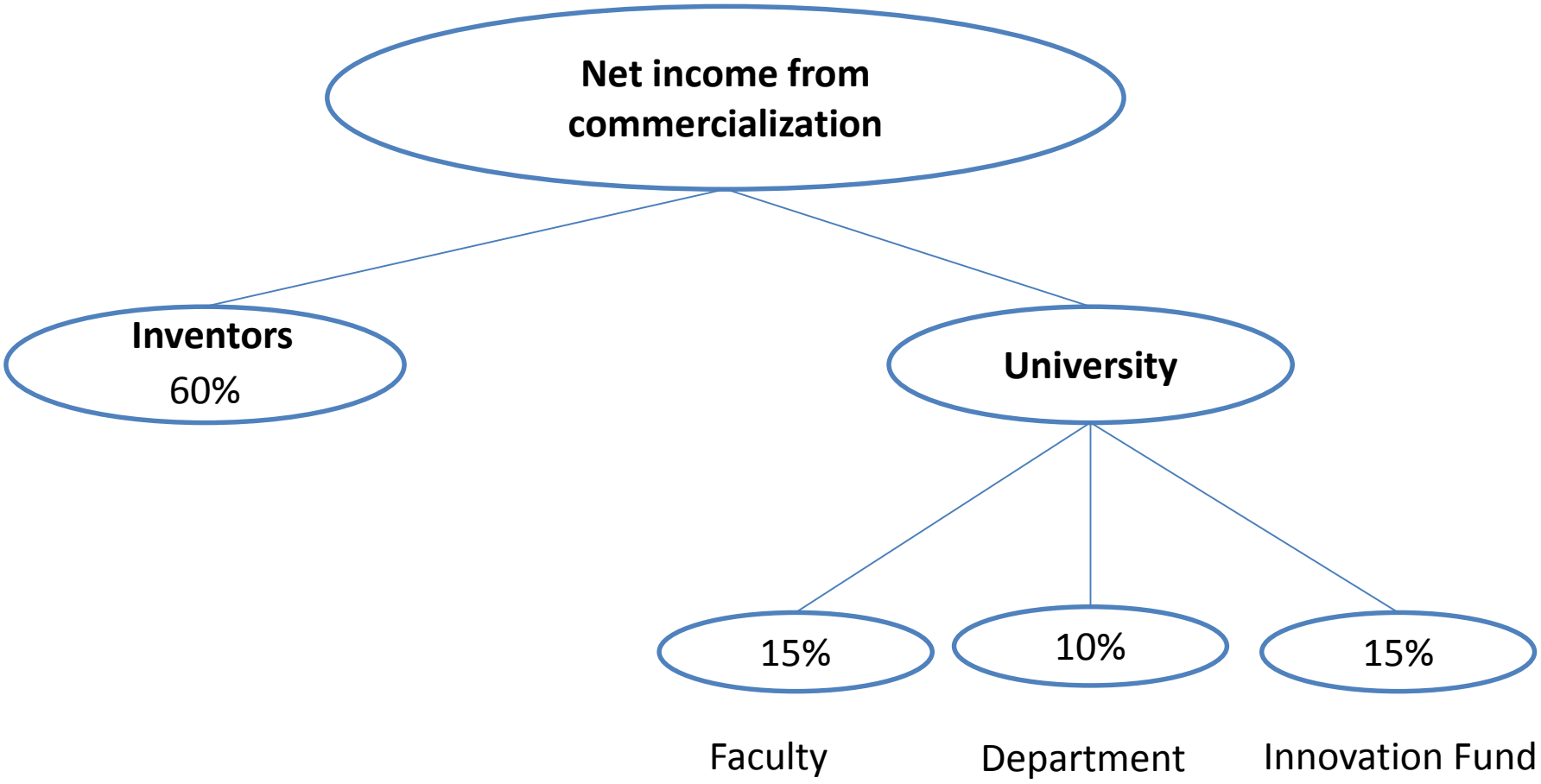
Simple business model of a university spin-off company

1. **Company formation**

2. **Transfer patent rights**: university transfers its patent rights to the newly-formed company — typically in exchange for equity and a license with royalty payments.

3. **University compensation**:
   a) Selling equity interest
   b) Royalty payments
   c) Dividend payments

Revenue distribution at University of Debrecen



Net income: patent costs, external costs of commercialization are deducted.

Google:
Start-Up Company from Stanford

The role of agreements in research management

Non-licensing agreements

- Confidentiality Agreement
- Material Transfer Agreement
- (Sponsored) Research Agreement
- Cooperative Research and Development Agreement (CRADA)
- (Scientific) Service Agreement
- Consortium Agreement (and also Grant Agreement)
- Consultancy Agreement
- Memorandum of Understanding (MoU)
- Space or Facility Use Agreement
- + any other type of agreement concerning research activity between industry and academia.

Confidential Disclosure Agreement (CDA)

Non-Disclosure Agreement (NDA), Secrecy Agreement, Confidentiality Agreement, etc.

Protects confidential information from public disclosure and unwanted use.

- Limits use and dissemination of information
- Compatible with patent procedure: disclosed information will not qualify as prior art
- A CDA is often the first step towards another agreement
- Generally accepted worldwide

Key requirements:

- The disclosed information should be marked clearly as „Confidential" in written form, even if it was originally disclosed orally or by any other means
- The scope of use of the confidential information should be clearly laid down.
- The term of the agreement should be separated from the term of secrecy.

Types: In, Out, Mutual

Material Transfer Agreement (MTA)

It is used to lay down limits on the transfer of (biological) materials from one *organization* to another.

- Limits use and dissemination of the Material
- Inventions may be created using the Material
- License may follow the transfer, but it does not occur often
- Often it is made free of charge, however certain costs may arise

Key requirements:

- The Material should be defined precisely.
- The scope of use should be clearly defined.
- Modifications – Ownership, use and distribution
- Ownership of raw research data
- Requirements for publication

Types: In, Out

(Sponsored) Research Agreement (SRA)

Used to establish the terms and conditions of a research project.

- Aims the implementation of a well-defined research plan
- Inventions may arise during the research project
- Care of the data rights and confidential information exchanged during the research
- Often includes an MTA and a CDA

Key requirements:

- Description of research work/project
- Invention ownership
- Publication of research results
- Payment terms

Types: Collaborative or Joint, Sponsored, Clinical

Scientific Service Agreement

Used to provide a scientific service for a third party by using or making available existing knowledge, expertise and/or infrastructures.

- It may consist of tests, measures, routine analyses, expert opinions, consulting, or provision of specific scientific equipment.

- Reports and raw research data are typical outputs.

- Generally no invention or other IP arise from this activity.

Interinstitutional Agreements (IIA)

Controls how research institutions will carry out technology transfer activities associated with jointly-owned inventions.

- Institutional roles
- Patent prosecution and costs
- Sharing licensing revenues

Key requirements:

- Appointment of the lead institution
- Sharing of patent expenses and revenues

Non-licensing agreements in technology transfer

Researcher's general perception:

- Administrative obstacle to research

However, it may have impact on:

- ownership and commercialization of Background and Foreground IP;
- patentability;
- publication;
- further research work.

Common points of negotiation

- Ownership of inventions
- Licenses, options, and other rights
- Ownership of data
- Publication of research results
- Patent prosecution
- Indemnification & liability issues

University of Debrecen

Center for Research Commercialization and Technology Transfer

Contact:

Tel: + 36 70 7091486

tbene@unideb.hu

http://techtransfer.unideb.hu

UD TECH TRANSFER