

EARLY STAGE INNOVATION IN **COUNTRIES IN TRANSITION**

Version One

Prepared by the Division for Certain Countries in Europe and Asia

WORLD INTELLECTUAL **PROPERTY ORGANIZATION**

page ii

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I. INTRODUCTION

- 1. The background and reason for launching this project was the increasing importance for national economies of intellectual property rights (IPRs) and in particular of academic IPRs. This resulted in a strong need for the appropriate management skills especially in those countries that have to date paid less attention to this question. During the WIPO Strategic Planning Meeting, in Moscow, on July 18 and 19, 2007 certain countries with transition economies requested a study on the subject. It is expected that the results of this project will serve as an important input for the promotion of long-term, permanent and sustainable growth and development of the economic performance in countries with transition economies. Our objective is to give university technology managers and innovation agents a practical tool, and so help develop the organizational background and human resources for the early phase management of innovation and transfer of technology from academia to the market place.
- In the framework of the present project we carried out a short survey amongst 2. universities and independent research institutions to discover the present practices and bottlenecks in the field of university IPRs management. Some of the analyzed results of the survey are included at the beginning of the corresponding chapter of this booklet. When elaborating on the questionnaire for the survey, our main objective was that the received prime data should be statistically easily analyzable. So with most of the questions the respondents had to choose out of pre-set options. Many of the questions were yes/no questions, so in these cases only 'yes' or 'no' could be marked. We show the number and ratio of the received 'yes' and 'no' answers on diagrams. In other cases the respondents could choose out of more options. These questions fall into two categories: quantitative and qualitative. In case of quantitative questions the respondents had to choose one of the given class intervals. We show the number and ratio of the received class intervals on diagrams. The respondents were not required to explain their choice of class intervals, so the explanation for the incurrence of outliers is usually not known. In case of qualitative questions the respondents could mark more than one option, so the number of answers may exceed the number of respondents and the diagrams should be evaluated accordingly. We would like to note that the presented best international practices do not necessarily demonstrate the results of the survey. The international best practices show how intellectual property management and technology transfer should work. Thus, the chapters very briefly cover the international best practice as a benchmark. When elaborating this tool we have tried to bring the information content of this material in line with the previous issues of the WIPO IP for Business series, and not to drill too deep into the details of the topic. At the end of the chapters we summarize our recommendations in 3 to 5 points.
- 3. We target this tool: at university technology professionals, scientists, IPRs professionals and patent attorneys, innovation agents and innovative SMEs who intend to promote their university liaisons.

- II. EARLY STAGE INNOVATION, RESEARCH AND TECHNOLOGY MANAGEMENT, TRANSFER OF TECHNOLOGY, A GENERAL OUTLINE
- 4. Even at the earliest stage of research there is a need for an understanding of IPRs, in two senses. First, researchers need to understand the IPRs context in which they are conducting their research so as to be aware of existing IPRs covering the area within which they are undertaking research. Second, the IPR potential of research needs to be understood as early as possible to ensure that IPRs are not inadvertently lost or compromised by way of premature publication for example.
- 5. The research context also influences the IPRs possibilities. Thus, contract research for a sponsor is likely to have IPRs built into the original sponsorship contract (requiring researchers to understand the nature of such contracts and negotiate to maximize their interests). Near market or applied research is most likely to have exploitable IPRs potential. "Blue sky" or pure research will require careful assessment as to IPRs potential in the medium to long term.
- 6. Given the many possible relationships between individual researchers, university authorities, and sponsors (when present), the question of IP ownership of research work needs to be made clear and recorded from the very beginning. It cannot be assumed that inventor/employee rules will always apply. Indeed, in the academic world it is likely that such rules do not apply.
- 7. The creation of the IP environment and the effective and profitable transfer of technology require an institutional framework involving government and the managers of research bodies. These institutions have to provide for trainers and advisors who will assist researchers understand how their work fits into the IPRs environment and system. Technology Transfer Officers or Organizations are needed to manage the process by which agreements between researchers and industry are negotiated and implemented.
- 8. Here we point out that different levels of regulation influence the process of transfer of technology. Figure 1 below is a short outline of this.

Figure 1: Levels of regulation of the IPRs management

International treaties and regulations				
National legislation				
Institutional regulation, IPRs policies	Agreements governing the international technology transfer of the universities (e.g. licensing agreements, R&D collaborations, consortia for supranational grants)			

9. The objective of intellectual property management and technology transfer is to assist the utilization and commercialization of economically valuable novel IPRs connected with research results into trade and industry. The term technology management includes all management activities that may be necessary for the utilization of a given technology. The innovation, intellectual property-focused technology management is a term broader than technology transfer in that it includes not only the actions necessary for transferring a technology (the flow between the inventor and those applying the invention) but the steps which take place before the actual transfer (research management) and those after it

(management of the technology's application, quality assurance, corporate management, human resources management, etc.) as well. The "technology transfer is the process of sharing of skills, knowledge, technologies, methods of manufacturing, samples of manufacturing and facilities among industries, universities, governments and other institutions to ensure that scientific and technological development s are accessible to a wider range of users who can then further develop and exploit the technology into products, process, applications, materials or services" (Wikipedia). Webster's: "Spread and adoption of inventions and techniques from one geographic area to another, from one discipline to another, or from one sector of the economy to another. For example, improvements in medical equipment may be transferred from industrial countries to developing countries, advances arising from aerospace engineering may be applied to equipment for persons with disabilities, and innovations in science arising from government research are made available to private enterprise." The technology transfer is the process of applying scientific research results in practical use. A number of companies, universities and governmental organizations have a technology transfer office (TTO) with the objective to identify research results that are of potential economic interest and to elaborate strategies for their utilization. Thus technology transfer organizations are of a multidisciplinary character, they employ scientists, engineers, economists, lawyers and marketing experts. The Massachusetts's Institute of Technology defines technology transfer as the movement of knowledge and discoveries to the general public. This can be realized by publications, employment of graduate students, exchange of experience on conferences and via industrial connections. The case when technology transfer is realized through licensing a technology towards a third party is of major interest, which licensing occurs by the cooperation of the university's technology managers, non-profit organizations and business enterprises (so called broker organizations).

10. Depending on the business model implemented, and the expectations of the partners, different kinds of TTOs can be established. In Figure 2 we outline the most common types (operational models). Here we note, depending on the type of a TTO, different skills, knowledge and human resources are needed.

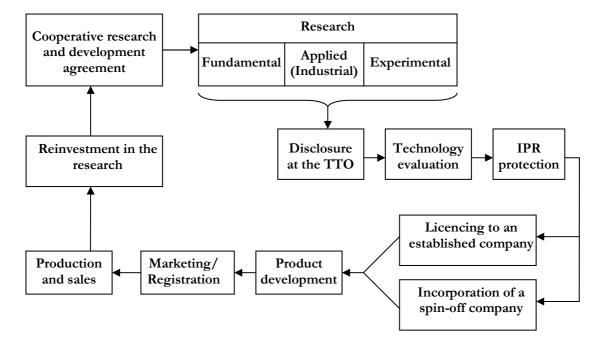
Figure 2: Possible types of TTOs managing academic intellectual property

Higher integration to one specific university	Lower integration to one specific university
University technology transfer department	Privately owned business enterprise
Business enterprise, owned by the university	TTO operating in an industry park
Spin-off incubator integrated to the university	National / regional innovation agency
university	

11. What advantages does transfer of technology possess? It has numerous positive impacts. Most important of those is probably the enhancement of the quality of life in the society due to the new technology, but the growth in economic competitive power, creation of high quality working opportunities, increasing of the financing resources of R&D, enhancement in the quality of education and the expansion of the freedom of science and research are also important.

- 12. The transfer of technology usually occurs in a framework of contracts, in which the contracting party is enabled to utilize the intellectual property (technology). The party receiving this authorization can be an already existing company or a spin-off company formed for this purpose. The contracts include the conditions according to which the authorization for the utilization is given, these among others include payment and the fulfillment of certain specific requirements.
- 13. The simplified process of technology transfer at universities is outlined in Figure 3.

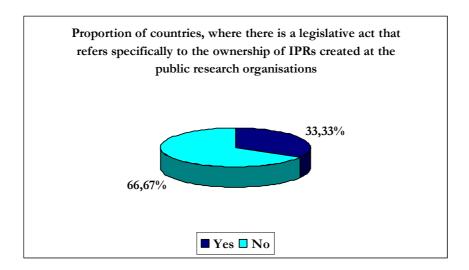
Figure 3: The simplified process of technology transfer at universities



III. SOME LEGAL ASPECTS OF IPRS MANAGEMENT AND TECHNOLOGY TRANSFER

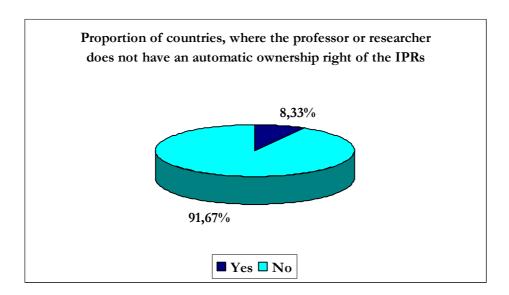
Fact: In the majority of countries there is no legislative act that refers specifically to the ownership of IPRs created at the public research organizations.

Figure 4: Proportion of countries, where there is a legislative act that refers specifically to the ownership of IPRs created at the public research organizations¹



Fact: In the vast majority of countries the professor or researcher does not have an automatic ownership right to the IPRs.

Figure 5: Proportion of countries, where the professor or researcher does not have an automatic ownership right of the IPRs²

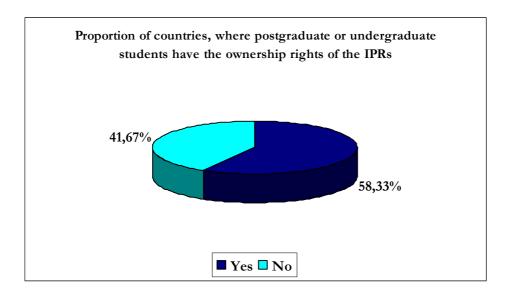


Fact: If postgraduate or undergraduate students are involved in the work which generated the IPRs, in the majority of countries they have the ownership rights to the IPRs.

¹ Number of responding research organizations: 12.

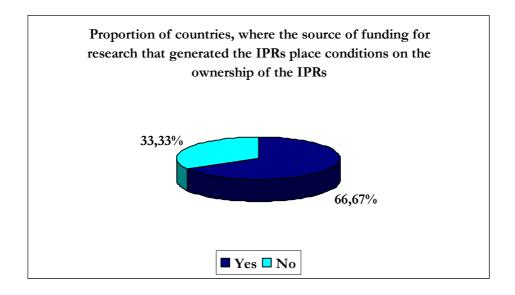
² Number of responding research organizations: 12.

Figure 6: Proportion of countries, where postgraduate or undergraduate students have the ownership rights of the IPRs³



Fact: In the majority of countries the source of funding (public or private) for research that generated the IPRs place conditions on the ownership of the IPRs.

Figure 7: Proportion of countries, where the source of funding for research that generated the IPRs place conditions on the ownership of the IPRs⁴

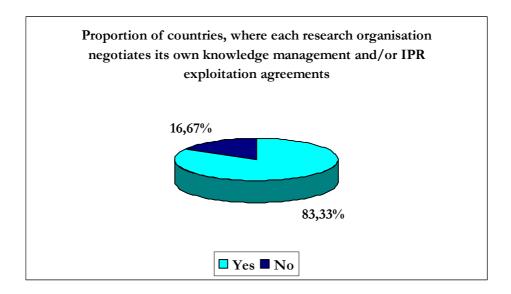


Fact: In the vast majority of countries each research organization negotiates its own knowledge management and/or IPRs exploitation agreements.

³ Number of responding research organizations: 12.

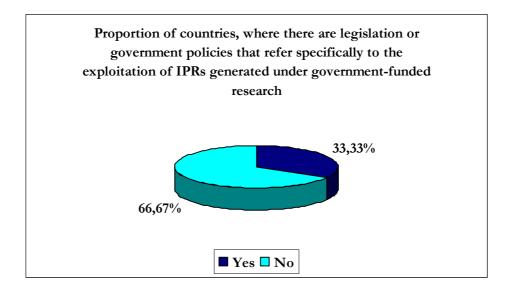
⁴ Number of responding research organizations: 12.

Figure 8: Proportion of countries, where each research organization negotiates its own knowledge management and/or IPRs exploitation agreements⁵



Fact: In the majority of countries there are no legislation or government policies that refer specifically to the exploitation of IPRs that are generated under government-funded research.

Figure 9: Proportion of countries, where there are legislation or government policies that refer specifically to the exploitation of IPRs generated under government-funded research⁶



14. The regulation governing the management of intellectual property has its own specific structure. The international legislation may include e.g. the international agreements, funding agency rules, etc. The national legislation usually consists of the IPRs law, including patents acts, the acts governing the other types of IPRs protection (copyright acts, too), innovation acts, furthermore, if they are enacted, the national programs of research, development, and IPRs management. Here we note, the national IPRs laws have a lot of specificities in their character, so a technology manager is well advised to be careful when designing the IPR

⁵ Number of responding research organizations: 12.

⁶ Number of responding research organizations: 12.

portfolio management. The third level of regulation is the level of institutional regulation. The most important documents are the university IPRs policies. These policies usually govern the specific rules of service invention (that is invention made in the course of normal duties), the ownership issues, and the revenue sharing between the university and the scientists. A sample IPRs policy can be found at

http://www.biopolisz.hu/uploaded/files/File/szte-ip_policy-en-2008.pdf. The lowest level of regulation is the level of contracts, including the employment agreements, job descriptions, R&D collaborations, consortial agreements, and every kind of technology transfer agreements, including licensing agreements, assignments of rights, material transfer agreements, etc. It is important to know that every valid legal source ranging from the act to a job description may have influence on the judgment of a legal situation. In the following we briefly introduce a piece of the European legislation specifically relating to the management of the academic intellectual property.

- 15. According to the EU Commission, state-funded research facilities produce the largest part of novel knowledge in Europe, though this does not bring significant economic results. Efforts should be made to better convert knowledge into socio-economic benefits. Therefore, public research organizations need to disseminate and more effectively exploit state-funded research results with an objective to translate them into new products and services.
- 16. The legislation affecting the technology transfer processes is part of the national legal systems. The EU Member States have in recent years taken initiatives⁷ to facilitate knowledge transfer at national level, but significant discrepancies between national regulatory frameworks, policies and practices, as well as varying standards in the management of intellectual property within public research organizations, prevent or hamper trans-national knowledge transfer. On EU Community level an initiative of the EU made a proposal for the elaboration and acceptance of a Charter for intellectual property management and this was accepted by the European Council in June 2007. The Commission accepted a recommendation on 10th April, 2008, titled C(1329)2008 Commission Recommendation on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organizations.
- 17. The recommendation formulates suggestions for the member states to foster the knowledge transfer processes and be more efficient at state-funded research facilities.
- 18. According to this, the member states should support among other things the adoption of intellectual property policies at the state-funded research facilities; foster the creation of technology transfer capacities and the enhancement of the IPRs consciousness; establish national strategies and directives according to those stated in the recommendation and take steps for elaborating any necessary legislation; take steps to foster the widest possible application of the practical guide that is a part of the recommendation; establish national contact points that would coordinate the actions related to knowledge transfer. The recommendation seeks to provide member states and their regions with policy guidelines for the development or updating of national guidelines and frameworks, and public research organizations with a Code of Practice, in order to improve the way public research organizations manage intellectual property and knowledge transfer.

⁷ See for example: Management of Intellectual Property in Publicly-funded Research Organizations: Towards European Guidelines (Expert group report – Office for Official Publications of the European Communities, Luxembourg, 2003

- 19. Formulation of the principles on the regulation of research, development and innovation (RDI) activities performed in partnership with other participants would foster more uniform and efficient cooperation both inside the member states and between countries. In questions related to IPRs protection in the legislation of the member states and third countries there may be parts for which those stated in the recommendation serving as some kind of a common reference could foster the establishment of international collaborations and more efficient operation. Accordingly, it seems reasonable that the contents of the recommendation be adopted by the governments of non-EU member states as well and the state-funded research facilities operating in these countries according to their own practices.
- 20. Annex Nr. I of the recommendation is a practical guide addressed to universities and other state-funded research institutions, grouping the principles to be implemented by the research institutes around three main topics: intellectual property protection, knowledge transfer and research collaboration and contract research. Among the most important aspects of the field of intellectual property protection are the following: development of an IP policy as part of the long-term strategy and mission of the public research organization; promotion of the identification, exploitation and where appropriate protection of intellectual property, in line with the strategy and mission of the public research organization and with a view to maximizing socio-economic benefits; provision of appropriate incentives to ensure that all relevant staff play an active role in the implementation of the IP policy.
- 21. Related to the promotion of knowledge transfer the following should be ensured: consider all types of potential exploitation mechanisms (such as licensing or spin-off creation) and all potential exploitation partners (such as spin-offs or existing companies, other public research organizations, investors, or innovation support services or agencies), and select the most appropriate ones. Ensure that the public research organization has access to professional knowledge transfer services including legal, financial, commercial as well as intellectual property protection and enforcement advisors, in addition to staff with technical background. Develop and publish a licensing policy, in order to harmonize practices within the public research organization and ensure fairness in all deals. Develop and publish a policy for the creation of spin-offs. Establish clear principles on sharing financial returns from knowledge transfer revenues between the public research organization, the department and the inventors.
- 22. As to the legal relationships for both research collaborations and for contract research, the following is advisable to be established: IP-related issues should be clarified at management level as early as possible in the research project, ideally before it starts. In a collaborative research project, ownership of the foreground should stay with the party that has generated it, but it can be allocated to the different parties on the basis of a contractual agreement concluded in advance, adequately reflecting the parties' respective interests, tasks and financial or other contributions to the project.
- 23. Annex Nr. II of the recommendation contains the summary of some best practices identified in the given topics. The application of these is to be considered by all not exclusively EU-member states. For example: the proper management of intellectual property resulting from public funding is promoted, requiring that it was carried out according to established principles taking into account the legitimate interests of industry (e.g. temporary confidentiality constraints). Where it is appropriate, a set of model contracts is made available, as well as a decision-making tool helping the most appropriate model contract to be selected, depending on a number of parameters. The pooling of resources between

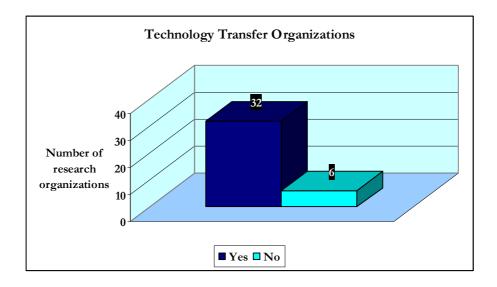
public research organizations at local or regional level is promoted where these do not have the critical mass of research spending to justify having their own knowledge transfer office or intellectual property manager. When signing international research collaboration agreements, the terms and conditions relating to projects funded under both countries' schemes provide all participants with similar rights, especially as regards to access to intellectual property rights and related use restrictions.

24. The management of IP policies in publicly funded research organizations is discussed in the following WIPO documents: Guidelines on Developing IP Policy for Universities and R&D Organizations; and Creating and Embedding on IPRs Policy in an Educational or Publicly Funded R&D Institution (Prof. Ganguli), the contents of which are hereby referred.

IV. TECHNOLOGY TRANSFER ORGANIZATIONS

Fact: According to our survey, in the majority of the responding research organizations there is a central body (e.g. department, TTO, etc.) within the organization that is responsible for IPRs management and technology transfer issues. The numbers are given in Figure 10.

Figure 10: Technology Transfer Organizations at universities and other PROs⁸



A. What do we call a TTO?

25. The technology transfer organizations (TTOs) are broker institutions with the mission to prepare and manage the commercial exploitation of scientific research results. The TTOs can be classified according to their function (IPRs focus vs. commercialization focus), status (university department, business company, etc, see: above), the skills of the human resources employed, their relationships with their partners (ownership, company-client partnership,

⁸ Number of responding research organizations: 38.

- etc.), etc. The character of a TTO thus can be more IPRs focused if it is a university department and more commercialization focused if it is a business company or one TTO operating in the industry. Furthermore, different skills may be required from one business model to another. The role of a TTO is usually to help inventors understand business processes in the most appropriate way.
- 26. Why is it necessary to mediate between research and industry? The players involved in the transfer are working in significantly different economic, legal, cultural and motivation environments. This often results in communications breakdowns among these players ("talking different languages") although due to the nature of innovation there should be a complementary relationship between research and industry. The re-establishment and maintenance of this cooperation is the mission of the consulting organizations which are:
 - (i) sufficiently independent from both parties so that they can be objective, and admissible for brokering;
 - (ii) constructed so as to have an overview of the real-life economical environment of both parties, "interpreting" between research and industry (understanding both parties' way of thinking and knowing the different interpretations of linguistic terms);
 - (iii) committed to the success of technology transfer.
- 27. As we see above, a TTO can be a business company or a university department (organizational unit). The organizational units only work for their university and its industrial partners, they do not compete with other organizations, their financing is from the university' central budget or from the relevant proportion of the university's innovation resources. Their advantage is that they suit the highly non-profit character of technology transfer and their operation can easily be financed. They are undoubtedly closer to the laboratories and have a better insight into the research projects. Their disadvantage is that it is more difficult to cope with conflicts of interest and the fixed financing and the lack of competition could eventually lower the work's quality. Being exempt from the market evaluation could eventually lead to the technology managers becoming "office people", which in turn reduces their drive to initiate. It is harder to manage a consortium with a lot of partners from a university's TTO.
- 28. Technology transfer (TT) companies can be affiliates of the university, that is the university could have a share therein but they can also be completely independent companies. External technology transfer companies provide their services on a business basis. They are formally independent, and therefore they compete with the other players on the market but they can manage more than one university, which in turn can lead to conflicts of interest. Therefore it is rare to have only one independent TT company managing the complete portfolio of a university's IPRs. Their business character is less suitable for the highly non-profit nature of technology transfer but it has a good impact on the service's quality and liability. In general the TTOs have the following missions and tasks, independently from the organizational set-up.
- B. The mission of technology transfer organizations
- 29. Through realizing the mission statement that summarizes the principles of their professional activities, the objective of TTOs in general is to:

- (i) foster the knowledge base and competitiveness of the university;
- (ii) enhance the attractiveness of the university as an R&D partner for industry;
- (iii) encourage the product-oriented, innovative approach and entrepreneurship at the university and its socio-economic environment;
- (iv) catalyze the creation of products and services from IPRs useful for the society;
- (v) create knowledge-intensive working places primarily by facilitating the establishment of spin-off companies as well as scientific collaborations with other institutions;
- (vi) ensure diverse, additional financial sources, including especially grants, seed capital⁹, venture capital¹⁰ and industrial investment capital to meet the financial demands of R&D and utilization.
- 30. The tasks of TTOs can be classified into two main groups, and one additional group. The first group consists of the research management tasks. These usually include the following:
 - (i) identification of the R&D results, evaluation of inventions;
 - (ii) research of the prior art (freedom to operate);
 - (iii) initiating IP protection, patent portfolio management;
 - (iv) tasks related to material transfer agreements;
 - (v) tasks related to research agreements;
 - (vi) cooperation in sharing the income from selling IP rights and the management of conflicts of interest.¹¹

"IX. The remunerations arising from the utilization, and the use of these remunerations

25. **§.** If the intellectual creation is directly utilized and/or sold, the inventors of the patent employed by the University shall be entitled to an appropriate invention fee, as defined in relating legislation in force and taking this Chapter of the Policy into consideration.

The invention fee is based on the following:

- a) When establishing of a direct utilization company: The invention fee shall be the fee based on the individual agreement between the University and the researcher(s), which cannot exceed the University's hare taxated net profit from utilization.
- b) In case of a license agreement: The invention fee shall be the license fee paid to the University, and other allotments measurable in cash regarding to this, except instruments, services and rights provided by the licensor to the University based on research or other agreements.
- c) In case of assignment contracts: The invention fee shall be the fees paid to the University, and other allotments measurable in cash regarding to this, except instruments, services and rights provided by the licensor to the University based on research or other agreements.
- 26. **§.** The amount collected first shall be used to cover costs related to the evaluation of the given intellectual creation and to the process of obtaining legal protection for the creation and its utilization and/or sale.
- 27. **§.** After reducing the fee by the costs described in Article 26, the invention fee shall be divided between the Innovation Fund and researchers, who contributed in the creation of the intellectual creation. The main rule of distribution is that the share of the Innovation Fund cannot be lower than 20 %, but cannot exceed 40 %, in accordance with an individual agreement. The share of the researchers should be paid within 60 days after receiving the invention fee."

⁹ Seed capital is given at the company's start-up phase, it is not a grant but rather an equity investment.
¹⁰ Venture capital means an equity investment of outstanding risk but also of outstanding yield prospects, into companies promising with significant growth. Venture capital is provided after the

start-up phase of the company
¹¹ An example for sharing the revenues as stated in an IPR Policy of a university is as follows:

- 31. The second group includes tasks that can be considered as typical technology transfer activities. These tasks are performed when the R&D results are already beyond the milestones reachable with research management. These are the following:
 - (i) technology transfer consultancy;
 - (ii) consultancy related to the assignment of the intellectual property;
 - (iii) consultancy related to the licensing of the intellectual property;
 - (iv) consultancy related to the management of spin-off companies;
 - (v) innovation marketing activities;
 - (vi) systematic industrial liaisons.
- 32. Tasks of the third, complementary group are the following:
 - (i) communication of the university's innovation activities;
 - (ii) teaching and training.

Figure 11: Case description: A TTO in a university town in Central Europe

Background:

BIOPOLISZ Ltd. was founded in 2003 by the University of Szeged, Biological Research Center (BRC) of the Hungarian Academy of Sciences, the Local Government of Szeged and Duna-Tisza Regional Development Co. Ltd. with the view of commercialization of the inventions created by the scientists of the university and the research institutes.

Fact sheet:

Shares of the members (expressed in voting rights):



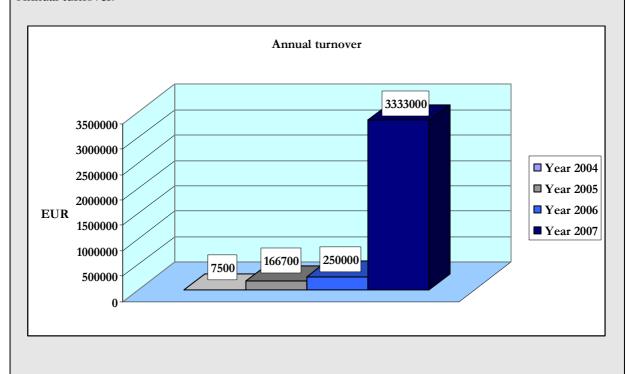
University of Szeged	26%
Biological Research Center (BRC)	26%
Local Government of Szeged	24%
Duna-Tisza Regional Development Co. Ltd.	24%

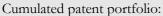
Business model of operation:

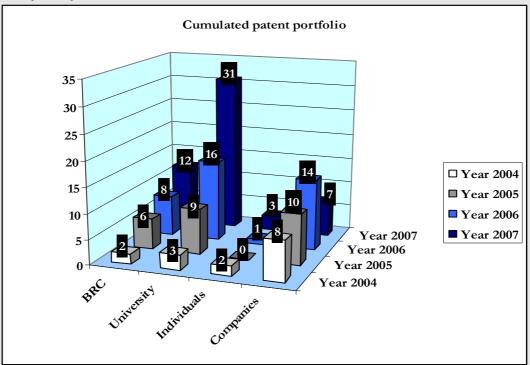
% of the annual turnover

Business consultancy 60% Hungarian grants 30% EU grants 10%

Annual turnover:







Other facts:

Average annual number of interviews with scientists to explore new technologies 100-200

Number of freedom to operate analyses completed in 2007 30

Average annual number of technology brokerage events, conferences, workshops 30

Average number of spin-offs generated annually 2005-2007 6

Number of technology licensing agreements managed in 2007 11

- 1. Membership in national and international organizations Hungarian Association for the Protection of Industrial Property and Copyright,
- 2. Hungarian Association for Innovation,
- 3. Hungarian Group of the Licensing Executives' Society,
- 4. Hungarian Biotechnology Association,
- 5. Hungarian Chamber of Commerce and Industry,
- 6. International Society for Professional Innovation Management (ISPIM),
- 7. Association of European Science & Technology Transfer Professionals (ASTP),
- 8. Association of University Technology Managers (AUTM),
- Technology Innovation Information (TII)

C. Start of the management: entrusting the TTO

33. Under no circumstances can a TTO perform any kind of management or representation activities without a written management contract. This is especially true when the subject is the management of a series of inventions or of the whole portfolio. This legal situation is arranged by the management contract. On one side of the contract there is the TTO, on the

other stands a university or an industrial company. The subject of the contract is usually the intellectual property at the disposal of the research institution, therefore it is advisable to attach the invention's specification available at the time of contracting as an annex. According to the management contract, the TTO undertakes to proceed with the necessary actions for the industrial utilization of the IPRs or the university.

D. Tasks of the technology manager

The substantive tasks of the TTOs are executed by the technology managers. The tasks of a technology manager can be summarized as follows:

- (i) assessment of the inventions, projects, contracts at the university;
- (ii) building a relationship with the innovative people at each unit of the university, estimating the possibilities for collaboration between the different units;
- (iii) keeping a connection, cooperation with the external experts, patent attorneys, lawyers working for the university;
- (iv) evaluation of the novel ideas and inventions sent to the TTO for their patentability and potential profitability, eventually with the involvement of external experts;
- (v) providing assistance for and consulting the university's scientists as to the protection of IPRs.

Summary:

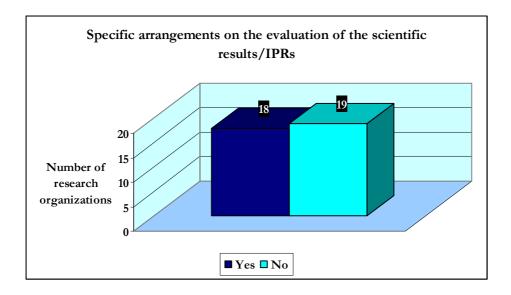
- 1. The **organizational setup** of the professional TTO should be chosen so that it best suits the expectations as to the quality and liability of the service, its for profit or non-profit character and the conflicts of interest.
- 2. Ensure the TTO's **proximity to the laboratories and projects**.
- 3. Ensure and train **human resources** with knowledge in technical/life sciences, law and business administration. The tasks of the employees should be defined so that they work on the projects in a team.
- 4. The **mission and objectives** of the TTO should be defined so that it best suits the institute's IPRs portfolio managed and that it ensures focused working.

V. RESEARCH AND ACADEMIC IPRS MANAGEMENT

A. The Identification, Evaluation, and Protection of the IPRs

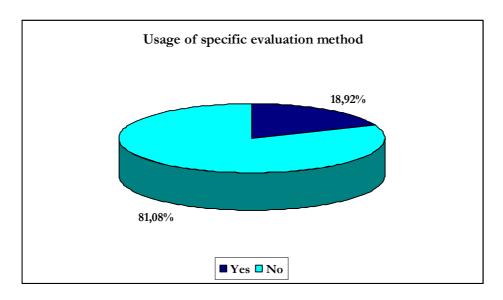
Facts: Our research shows that only half of the responding organizations employs any specific arrangement on the evaluation of the scientific results before protecting or exploiting an IPRs, see Figure 12.

Figure 12: Specific arrangement on the evaluation of the scientific results/IPRs¹²



34. As to the established evaluation methods, the situation is even worse: more than 80 % does not use such a method, as it can be seen in Figure 13.

Figure 13: Usage of specific evaluation method¹³



35. The initial activities of TTOs can be modeled with a well-defined, linear process. The TTO is the primary and confidential gate for the researchers for disclosing novel ideas and inventions before publishing them; this is the passive reception of novel intellectual properties. The office is also actively searching for intellectual properties, research results, ideas and inventions of economic potential. (At this point the involvement of the invertors is expressly emphasized.) A form can be applied in both cases, this is called an invention disclosure form. This form is not identical with the detailed invention disclosure form which is a more detailed document and which is not filled in along the first interview but only later

¹² Number of responding research organizations: 37.

¹³ Number of responding research organizations: 37.

on. This is because according to general experience the first interview is not suitable for the clarification of all details related to the invention, and is not necessary either: from a short technical information sheet of 1-2 pages and some other circumstances it is possible to deduct whether at that moment there is need for the technology manager's further cooperation. Preferably this brief invention disclosure form does neither require nor allow the disclosure of non-protected, confidential technical information and thus it is not a confidential document: it can be communicated also as "flyer" to potential investors. In case of a promising subject, with the involvement of the inventors and external experts the TTO investigates the possibilities for legal protection (e.g. patentability) of the ideas (inventions), then also with the involvement of the inventors and external experts assesses the potential exploitability of the novel ideas (inventions). For this we need the detailed invention disclosure form which does ask about all the relevant information on the technical, legal and economic aspects of the intellectual property. Therefore the detailed invention disclosure form is a confidential document, the office can only communicate it towards a third party, especially towards an external expert when a non-disclosure agreement has been signed. The detailed invention disclosure form contains among others the following: data on the invention and the inventors, including especially the technical content of the invention; the invention's ownership rights, its service invention character, a third party's prerogative, contract-based rights over the invention, chronology of state funding related to the invention, private equity used for the creation of the invention, etc; facts related to any former publication of the invention, plans related to future publications; known patent and non-patent prior art related to the invention; known researchers and businesses active in the field of the invention; ideas on commercialization.

36. Having performed the first patentability test, the TTO elaborates, initiates and supervises the patenting process. During this process, they keep contact and tightly cooperate with the patent attorneys. It is the TTO representing the research institution as the owner of the patented or other IPRs along the patenting and all other processes related to IPRs protection. They monitor any eventual unauthorized exploitation of the research facility's intellectual property by third parties, and (by employing a patent attorney or a lawyer) take precautions for professionally inhibiting such. In addition it is the responsibility of the TTO to manage the patent renewal process. Attending to the related tasks the office applies the provisions of the Intellectual Property Policy and directs the attention of the owners of the projects if of the policy occurs.

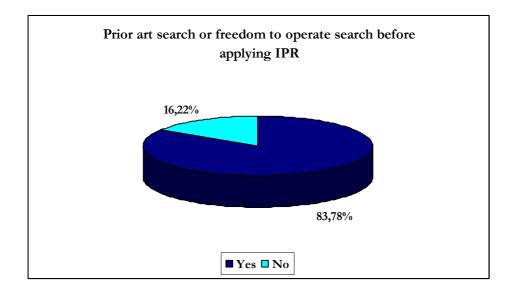
Summary:

- 1. Use a unified protocol for the identification, evaluation and protection of the technologies.
- 2. Test the patentability.
- 3. Clarify the ownership issues, and the IP rights of the employer, the inventors and third parties.
- 4. The preliminary technology assessment should be limited to the rough estimation of the market of the anticipated products/services. Using of secondary market information is sufficient.

B. Research of Prior Art

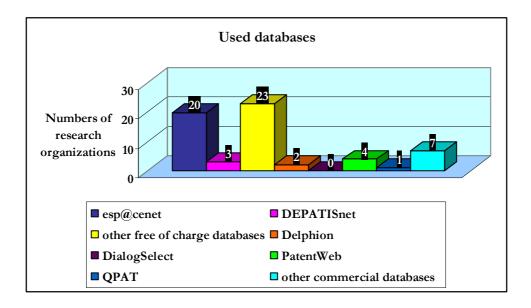
Facts: A positive phenomenon is that most responding research organizations perform prior art search or freedom to operate analysis before utilization of an IPRs. The proportions are illustrated in Figure 14.

Figure 14: Prior art search or freedom to operate search before applying IPRs¹⁴



37. At the responding research organizations, Esp@cenet is used most often (66,67%) from among the named databases, however, searching in other, not named free databases is also wide-spread (76,67%). The commercial databases are a lot less exploited. Utilization of the later was only mentioned in four countries (see: Figure 15).

Figure 15: Used databases¹⁵



¹⁴ Number of responding research organizations: 37.

¹⁵ Number of responding research organizations: 30.

The prior art¹⁶ is searched for various reasons. During the official patent examination 38. process a patent examiner performs a novelty search to complete the Search Report on the patentability of the invention. The prior art is also searched by the inventor when orienting himself on the technological background of his field of expertise. The patent attorney is doing research in order to elaborate the state of the art chapter in the description. The prior art search performed by the technology manager also has different levels. A not too precise, not all-inclusive search is done when the goal is only getting informed in the technological field or when assisting the patent attorney to complete the patent description. The research after the patentability test covers all circumstances however, as it will be used to decide on the protection and exploration. The freedom to operate analysis defines if others' IPRs are infringed in case of practice of a certain invention. In such cases only patent information is investigated and even within patents neither the non-valid, expired IPRs nor those protected outside the targeted market of commercialization are considered. (Here we note, in cases of prior art research and freedom to operate analyses, liability issues may arise at the consulted searching professional's end.)

a) Information barrier

39. One can get information on many different ways. When the information acquired serves as a basis for some kind of action, for example we intend to gain patent protection, expectations regarding the sources of information are higher. The most basic requirements are that the databases are systematically ordered, easily researchable, reproducible and controllable. These requirements are especially valid for the online patent databases. However, it is important to know that even the most logically built, perfectly updated databases depend on the input provided. Patent applicants usually give information differently (with non-uniform vocabulary) and sometimes (on purpose) in such a way that some important parts remain hidden¹⁷. We note here that – partially due to the above reasons, partially because those maintaining the databases themselves do not take the responsibility either for consequences of using their database –, it is of key importance to inform the clients about the circumstance that the technology manager performing the search cannot take any responsibility for their decisions based on the results from this search.

b) Search strategy

40. Apart from finding information relatively easily through online sources we must stress the careful design of our search strategy. A search that is not thought through can result in useless and in missing relevant research documents (hits). In most cases too few hits or missing hits mean that the applied keywords were not appropriate. The searching professional must realize that there can always be relevant information that was not identified. Thus it is recommended to redo the search from time to time with the same search principles. A follow-up search is also very important because patent applications are only published after 18 months from the date of priority or, in the case of many USA applications, on granting. Thus information that is eventually novelty destroying, filed on the day before our prior art search may become known to us only 18 months later.

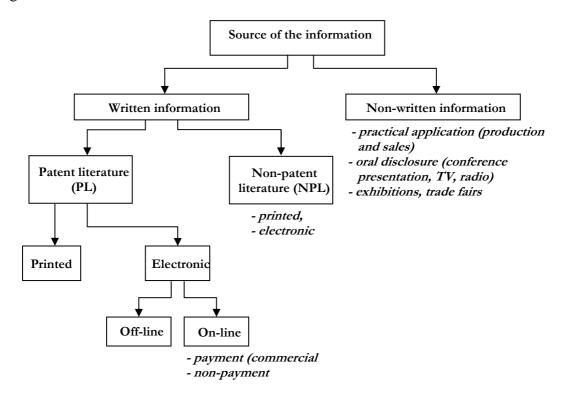
¹⁶ Prior art encompasses all known technical solutions in the field.

¹⁷ It is a simple trick to disclose the name of a complicated chemical substance in such a way that instead of the generally accepted nomenclature they use the rare, however still official name or a pharmaceutical name that is often used, however not informative on the chemical structure.

- c) The importance of reproducibility
- 41. A search report that only provides the information acquired is of no value. It is important to document the applied search strategy as well as the keywords and search questions, since this way the client can verify the relevance of the hits.

The information sources are summarized in Figure 16.

Figure 16: Source of the information



- 42. From among these some are unavoidably not considerable by the technology manager performing the prior art search, such as oral disclosure, practical application and most often presentations on television or radio.
 - d) Patent and non-patent documents
- 43. The documents can be grouped into patent and non-patent documents. The patent literature is of a more uniform structure as compared to other descriptions (for example there are units that cannot be missing from them, such as the claims giving the scope of the protection and the examples showing technical implementation), and through the archives of the patenting offices theoretically it would be possible to investigate the full patent literature. The gigantic patent databases bring us closer to this ideal situation, however we must note that a perfect prior art search in respect to all documents ever disclosed and the optimal result from this search, that is we would find all knowledge including non-patent literature documents as well cannot be performed in practice. Patent literature documents include primarily the patent descriptions, publication documents, publications from IP offices and other official publications containing information related to inventions. When searching in patents it is advisable next to using keywords to narrow the searched field of technology by using the International Patent Classification. Non-patent literature documents include

books, professional journals, referring journals and other printed materials. The Internet provides access to vast, structured databases in this field as well. Publications from industrial companies, reports on the work of scientific institutions, materials from scientific meetings and presentations, non-published dissertations accessible to an undefined group of people (e.g. in a library), plans, grant applications, etc. are those other printed materials over which the prior art search may be eventually extended. In referring to any document relevant to the prior art it is a basic condition that public access before the priority date of the application is definitely stated and verifiable.

e) Electronic data sources

44. There are two basic types of electronically available databases, the local (optical disk) databases and the remote (online) databases. The advantage of optical disk databases is the full safety during the search, i.e. unlike using an online database no information technology attack is possible on the search for finding out the keywords or other search information. In certain cases this can be of utmost importance. The advantage of online databases is their easier access, disadvantage is the vulnerability.

f) Information on the Internet

- 45. With the Internet being more and more developed it is now possible to make at least superficial estimations on the inventions' novelty. Novelty searches usually begin with the general investigation of the invention's subject. This is important so that we get acquainted with the terminology used by the experts of the given field. Optional sources for such search are the search engines ¹⁸ or the Wikipedia project¹⁹. The significance of the Internet is that whilst "traditional" information sources are usually relatively hardly accessible through libraries, patent archives, etc, the Internet gives direct access to both the patent and the non-patent like information.
- 46. When using patent information sources from the Internet, it is indispensable to clarify what sort of documents are included in the given database and what kind of a search strategy can be applied for our search. In general, free information sources are of no competition to the commercial databases since either their searchable document-repository is smaller or the possible search methods are more restricted. The EPO database "esp@cemet", http://ep.espacenet.com/ is an exception as is WIPO patentscope® http://www.wipo.int/pctdb/en/index.jsp. Determining and proving exactly what kind of information is accessible when and by whom on the Internet (that is whether the information can be considered as part of the prior art or not) is considerably harder due to problems in documentation and the fast changes to which the Internet is subject.
- 47. Information from the Internet can be considered accessible without personal restrictions if the Webpages containing the information are possible to be found not only by hazard but the URL is publicly available (for instance a publicly available paper-based document discloses it or another public webpage is referring to it, etc.), or one can find them with an Internet search engine. Password protection or the information being encrypted is only excluding the website from being part of the prior art in case it serves keeping the information confidential. It is not an excluding factor either if the information can only be acquired in

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¹⁸ E.g. Google http://www.google.com, Yahoo http://www.yahoo.com, etc.

¹⁹ http://www.wikipedia.com

return of a payment. In case the information is part of an electronic mail, contents addressed specifically to a private person (independently from being encrypted or not) cannot be considered as accessible without personal restrictions, however the contents of a mail sent to a public discussion group or a chat-room are.

- 48. The date of disclosure of the information is usually stated in some form in the Internet document. In case of trustworthy information providers (for example well-known publishers, academic institutes, international organizations, etc.) the date missing from the document in question can be substituted with an authentic declaration from the information provider. In case of "trustworthy" information providers we can presume the authenticity and originality of the information that is the information content at time we found it is identical with the information content on the Internet at the time it was published²⁰.
- 49. It is worth a reminder that due to the open nature of the Internet without taking special precautions there is elevated risk that unauthorized persons could be watching our search strategy and make assumptions on the subject of the invention before its official disclosure.

Summary:

- 1. The IPRs search should be performed according to a uniform protocol in a reproducible way. The specific steps to be done within the protocol can be more or less the same, however, the meritorious analysis of the search results will be done by the technology manager.
- 2. Besides using keyword search, use the **International Patent Classification** and search the inventors in the databases. By the later practice, one can faster find self-novelty destroying documents.
- 3. Conciliate with the inventors on the keyword-combinations, but keep them a secret from everyone else. The keyword-combinations are to be handled as confidential know-how.
- 4. If we get a lot less than 50 or a lot more than 500 hits for our search, it is advisable to reconsider our search strategy.
- 5. **Analyze search hits** thoroughly.
- 6. **18 months after** the first search **perform a follow-up** search with the original search strategy.
- 7. Consider the limits of the databases and search engines used for your search. Carefully read the general terms and conditions of the applied database's maintainer.

 Communicate the uncertainties and limits of the search to the client.
- C. IPRs Protection and Portfolio Management Issues
- 50. The present tool does not contain a description of the intellectual property protection types, we herein only recommend the WIPO IP for Business series²¹ from the units of which one can get acquainted with the different protection types as well as the basic principles of a

²⁰ We remark that information gained from the Internet is also concerning the work of patent examiners. The way of referring to documents gained from the Internet and included in the prior art search report is part of the WIPO ST. 14 recommendation.

²¹ http://www.wipo.int/sme/en/managing_ip.html

licensing agreement. The tasks of the technology manager in the field of patenting are on one hand rather limited, on the other hand the employment of a patent attorney can never be omitted. The tasks of technology management can be divided into two main groups: creating a patenting strategy and management of the patent portfolio.

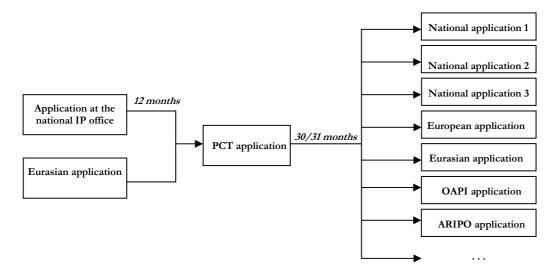
a) Service inventions

R&D and inventive work at the universities is usually performed by researchers who are in an employment contract with the university. A service invention is an invention of a person of whom it is an obligation of his job description to develop solutions within the invention's subject matter. In the case of an employee's invention there may be no such explicit job description but the exploitation of the invention may be within the university's scope of interest. Contractual obligation is often not explicit in the contract of employment; the university's intellectual property regulations and IPRs policy and also often the provisions of the university's collective contract have to be taken into account. It is not uncommon that the researcher considers the IPRs as his own property and his R&D activities as an "intellectual hobby"; the professors' privilege is even a tradition in certain countries. It is the task of the TTO to investigate the exact IPRs ownership related to the invention, to clarify rights and obligations originating from employment and to ensure the administrative steps to be taken by the university as the assignee of the service inventions. The TTO has to ensure as well that the inventor receives his invention award or gratuity, in line with the university's intellectual property regulations. The university as employer must certify the transfer in writing and within the time allotted declare whether it claims its part of the rights (and obligations) in respect to the service or employee's invention.

b) The IPRs Protection Strategy

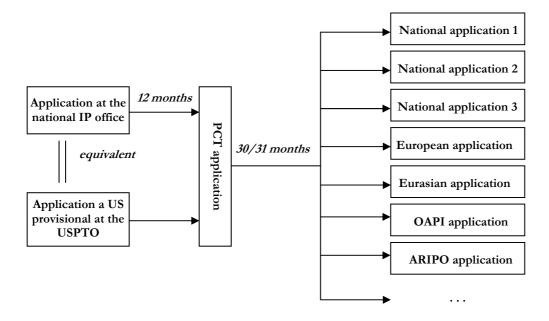
- 52. The patenting strategy and especially the first patent application strategy has to be in accordance primarily with the utilization plans for the invention, the targeted market, the planned schedule of entering the market, etc., and secondly with the publication strategy of the researcher. In general it is advisable to formulate the first patent application in English language and if enabled by the national patenting legislation file it in English to the national IP office. It is a general rule as well that publication can never precede patent application, but the safest is to plan the publication at the end of the priority year so that the developments performed in the meantime can be inserted into the international patent application. However, the publication pressure on researchers rarely enables the later in practice. We review some patenting strategies below.
- 53. It is a simple process to do the priority application at the national IP office. If we are likely to enter international patenting prosecution we can drop the priority application from financial considerations. With this process one can gain a relatively significant time since besides the priority year there is also the time of the PCT prosecution that is in total 30-31 months for developing a national patenting strategy (Figure 17). The delay until month 30 to 31 counted from the priority application can be justified if the applicant intends to keep the costs at a reasonable level until he decides on the IP strategy (territory) in view of the market opportunities and the results of patent searches.

Figure 17: Patenting strategy starting with a national patent application



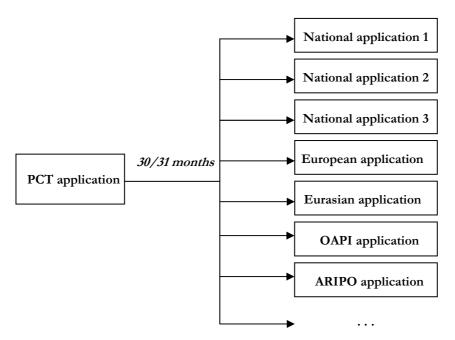
54. If we intend to target the market of the USA with our invention, it is advisable for the sake of convincing potential American investors to make a US provisional application as well with the same priority date as the national application. Equivalent priority documents are created this way. The application can be filed electronically and does not require a US legal representative and the costs are also low. The equivalent priority documents are apparently unnecessary: in the American interference prosecution the national priority documents (preceding the PCT documents) do not count as American disclosure, however the US provisional document does so (Figure 18).

Figure 18: Patenting strategy using US provisional application as well



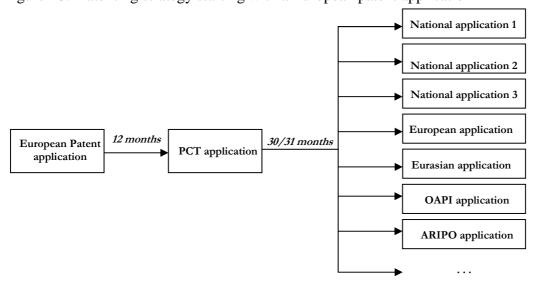
55. One can save time by directly filing a PCT patent application. In this case the national phases start after 18-19 months but we shall also have the International Search Report and the International Preliminary Examination Report of the PCT prosecution, thus we can make our decisions on our future strategy (Figure 19).

Figure 19: Patenting strategy starting with PCT patent application



56. If it is mainly the European market where we intend to exploit the invention, a European patent application can be filed as well. In this case we usually have the European Search Report within six months, this document is a suitable basis for a decision whether to start the PCT prosecution or not (Figure 20).

Figure 20: Patenting strategy starting with a European patent application



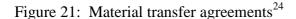
- c) IPRs Portfolio management
- 57. The intellectual property portfolio management is a series of actions preparing decisions and of decisions so that the university or any other organization having IPRs will have the most profitable portfolio of patents and trademarks of the highest possible value whilst keeping the costs within reasonable limits. Within the framework of this, decisions are due among others on the following:
 - (i) whether to implement the rights over the service or employee's inventions disclosed by the researchers;
 - (ii) whether the geographical strategy is in harmony with the licensing strategy;
 - (iii) whether to make use of the delays enabled by the patenting prosecution;
 - (iv) whether to on drop the patents of low profitability or transmitting all rights over to the inventors free of charge and on eventually setting and practicing option-rights related to these patents.
- The involvement of the applicant in the preparation of decisions is compulsory and it is 58. advisable (sometimes compulsory) to involve the inventors and the patent attorney as well. The principle of portfolio management is that the protection strategy should be in line with the business objectives and considerations. We should be aware of the fact that patenting is a very costly process and the involvement of even only one more country in the geographical strategy can significantly increase the costs. Thus the technology manager should warn the decision-makers to plan the patenting costs into the project's R&D budget. Patent portfolio management is not only the analysis of our own portfolio but includes the constant follow-up on the changes of our competitors' portfolios as well. The information we can gain this way could be a basis for very important conclusions. Positive progress of our competitor's portfolio could result us in losing market share and devaluation of our own portfolio. The decline of the competitor's portfolio may bring us possibilities in expanding our market share but it could also mean that the given sector of technology has lost its significance, for example due to a new-generation technology, and that our competitor has reacted to the phenomenon faster than us. In such cases following the competitors that is dropping our own portfolio can be a justified step as well.

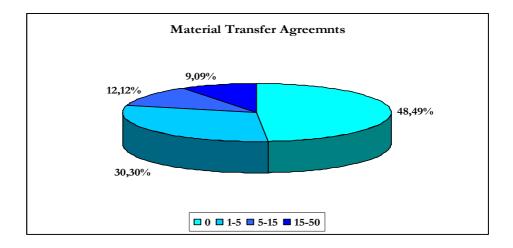
Summary:

- 1. The patenting strategy should be **harmonized with the ideas on the invention's exploitation** and with the **publication objectives** of the inventors as well.
- 2. For priority applications **it is not always advisable to follow the same procedure**, nor it is the most cost-effective process that is the best for us, thus before bringing this decision all circumstances (such as especially the targeted market or the geographical strategy of the competitors) are to be carefully analyzed.
- 3. The priority application strategy limits the flexibility of the patent portfolio management, thus it is advisable to **plan for a longer period of time**. In accordance with the portfolio management the priority application strategy should be optimized with regard to the circumstances that have meanwhile arisen and to our financial possibilities.

- D. The Management Material Transfer Agreements (MTA) and of Research and Development Agreements
 - a) Material Transfer Agreements
- 59. According to the UNICO Practical Guides²² a material transfer agreement (MTA) is a contract governing the transfer of materials between researchers. The supplier/provider of the materials is usually an institution owning the materials but may sometimes be an authorized licensee. The range of the materials generally falls within the biological/chemical category (such as transgenic animals, cell lines, antibodies, drugs, etc.). The provider gives the materials to obtain benefit, but more usually with the view to generating data on the materials. The recipient will pay for the materials and usually uses them to carry out further research with them, or to evaluate them to determine whether to enter into further agreements (such as research or licensing agreement).

Fact: Most of the responding research organizations do not sign a material transfer agreement or other such agreement and also the rest of the research organizations only sign very few of them. The annual number of such agreements does not exceed fifty per research organization and even fifteen is only exceeded in case of three research organizations (Figure 21) 23





60. The contract defines the rights of the recipient and the provider with respect to the material and its derivatives. There are the following types of material transfer agreements in case of scientific institutions: transfer between a university and a research institution, between industry and a university or a research institution. In case of research materials this

UNICO Practical Guides; Commercialisation Agreements – Material Transfer Agreements; www.unico.org.uk

Such experience is probably due to that material transfer agreements are related to a specific group (biological materials) of research materials. Those research organizations answering which are active in the field of for example technical sciences definitely do not sign any material transfer agreements.

²⁴ Number of responding research organizations: 33.

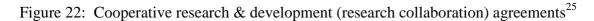
means a subject matter of high added intellectual value but usually of no patent protection (it is often not even possible) and the related research information, thus it should be ensured that the transferred materials can only be used according to the restrictions stated within the material transfer agreement, within strict boundaries, according to a given objective and with the exclusion of third parties.

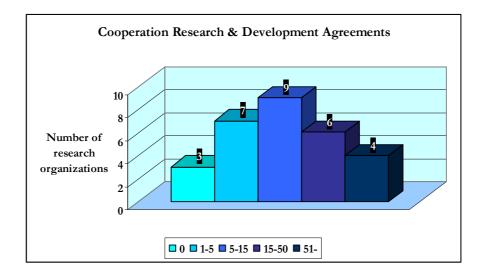
- 61. We should already at this point draw distinction between an MTA and a licensing agreement. A licensing agreement governs the exploitation of a protected IPRs; including primarily production, multiplication, distribution and sales and often sub-licensing as well. An MTA does not allow such commercial multiplication, distribution or granting availability to others. In this case the objective is the transfer of certain materials in defined amount necessary for additional (eventually collaborative) research, according to a defined objective.
 - b) Contents of the material transfer agreement
- 62. As to the MTA's contents, it first has to be defined what the parties consider as material; this can be the original material, an unmodified derivative or a progeny. The rights of the recipient have to be detailed, especially that the recipient can use the material only for non-commercial purposes or in case the recipient destines the material for commercial exploitation then similar clauses as in a license agreement (upfront, milestone, royalty, yearly minimum fees, margins, etc.) should be enforced. The confidentiality clause is often stated in an MTA, in accordance with which the recipient acknowledges the confidential nature of the information related to the transferred materials. However the information necessary for evaluation of research results gained along using the given material should be communicated towards the recipient party.
- 63. In relation to the warranty, it is usually part of the contract that it is not extended to vendibility, suitability to special purposes or that utilization of the material would not infringe patents, trademarks, copyrights, etc. The provider shall not be responsible for the damages, expenses, losses that are the result of use, handling or storage by the recipient, except for the expenses, damages and losses which can be traced back to the provider's neglectful or malicious conduct. Apart from these the provider's access must be ensured to the recipient's articles, for example in such a way that within not less than 30 days prior to publication the manuscript must be given to the provider, thus he has the possibility to protect its IPRs from the publication. In return for this, the provider undertakes the responsibility to keep the copies confidential during the 30 days' term and until publication. Furthermore it is advisable to arrange the provider's rights over the recipient's research results and inventions in the MTA (one possible way is when the recipient party may file a patent application for his invention using the original material, but the recipient should notify the provider).

Summary:

- 1. In general we do not recommend using model MTAs since these have many possibilities of error and are most rarely suitable for reaching the real objectives of the transfer. Instead it is better to use a **checklist**. This lists the aspects and clauses are not advisable to be omitted from the negotiations and from the contracts.
- 2. The contract should **exclude the provider's warranty** on the transferred material being technologically suitable for realizing the objectives of the recipient party, as well as the warranty that a third party would have no rights which could obstruct or limit utilization.
- 3. It is advisable to state that the publication of research by utilization of the materials is only possible with preliminary reviewing by the provider, furthermore in case the materials are intended to stay confidential then in a publication the description of the transferred materials must be omitted.
 - c) Cooperation Research and Development Agreements (CRADAS)
- 64. The CRADAs are contracts between an industrial partner and a university that performs a sponsored research while the industrial partner pays and acquires ownership of the IPRs created. In fact, if a research institution receives a national (or European Community) grant then the contract with the funding authority and the paralelly existing consortial agreement with the consortium's industrial partners are also to be considered research agreements. The process can be called research collaboration, as well.

Fact: Most responding research organizations sign CRADAs. For most research institutions the annual number of research agreements signed exceeds five. The number of agreements exceeds fifty in case of four research institutions. Compared to the other examined types of agreements (material transfer agreements, agreements on the assignment of IPRs, technology licensing agreements), the estimated annual number of agreements is the highest in case of CRADAs (Figure 22).





²⁵ Number of responding research organizations: 29.

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- 65. A cooperation research and development agreement offers the following advantages:
 - (i) enables the university to supplement its budget and optimize its resources;
 - (ii) provides methods for sharing technological expertise, ideas and information in a protected environment;
 - (iii) enables both parties to share the IPRs created along their collaboration or to ensure exclusive license based on their agreement to one of the parties for patentable research results;
 - (iv) fosters commercialization of the developed technology.
- 66. The process of concluding a research and development agreement starts with preliminary negotiation of an industrial organization and a budgetary research organization due to their mutual interest in a certain field of technology. The next step is to elaborate a workplan together; this outlines the responsibilities of the parties in a research agreement. The full workplan supplemented with the relevant legislations constitutes the research and development agreement which comes into force by both parties signature.
- 67. As for the relation between the above described MTAs and CRADAs, these are almost never independent from each other but the dynamics of the actual cooperational relations significantly influence the realization. For instance the MTA can be a document governing the transfer of a product resulting from a successful research contract that is an agreement following the CRADA. It is also possible however, that already in the research agreement the conditions for material transfer are stated, in this case the material transfer is a part of the research and development agreement. In certain cases the research and development agreement does not contain any material transfer, in other cases the material transfer is not accompanied by a research collaboration, but these are rare cases.

d) Contents of a CRADA

- 68. Like every contract, a CRADA also has to regulate in most details possible the rights and obligations of the contracting parties. It contains such provisions that are primarily regulated by the institutional IPRs policy (if there is such) and legal regulations, to protect the social interests connected to the transparency of research and development and the rightful ownership of results. We mention here that the legislation of the European Community specifies very severe competition law for such clauses of the CRADAs which offend the principles of fair competition.
- 69. The CRADA makes provisions on financing which can be solved in a number of ways. The company can undertake the whole financing but it can be shared between the contracting parties as well. In general, the contract ceases with the fulfillment of the research work, however it can be modified if there are additional research to be done or if the time meant for fulfillment is prolonged. Moreover, the CRADA can be terminated with the written notification of either parties. The confidential information as business know-how needs protection. Therefore it is advisable to put a confidentiality clause into the CRADA. Provisions and obligations related to the non-disclosure of information are negotiated between the contracting parties. Furthermore, the information created along the fulfillment of the CRADA can be protected from disclosure also after the termination of the contract for a defined period.

- 70. It is also necessary to govern the liabilities in the agreement, with special attention to the warranties connected to the performance of the research. The CRADA can exempt the central budget research facility from all costs related to such personal injuries or financial losses that are originating from the use of the products, processes or services created by the research. The CRADA cannot be an obligation for positive results²⁶, therefore a properly documented research work performed in good faith and due diligence, but lacking positive results does not raise any questions of liabilities and it is a basis for claiming the research fee. Naturally the industrial side tends to give more of a "subcontracting" character to this type of contract; and research methods are developing in such directions that the requirement of such subcontracting nature is not necessarily without reason. Since the well-reproducible, standardizable and analogue measurement methods enable predictable results, requiring a positive result related to this usually does not put unfair pressure and responsibilities on the researcher. Sometimes the sponsored research itself is such that does not require any special creativity and it is only about the fact that the instrument applied in the research is owned by the university.
- 71. As to the rights related to intellectual property, it is general rule that all inventions which were created exclusively by the participation of the company becomes its property whilst the inventions developed exclusively by the research institution become the property of the research institution. In case of the jointly discovered inventions the contracting parties gain rights according to the proportion of their participation in the invention's development. However one can deviate from this; it often happens that the company acquires all IPRs in return for certain payment. It can also occur that the company participating in the research agreement has the option to use the invention. The so-called first right of refusal is a clause which means that someone has priority to take or refuse. The so-called first look option means the right of evaluating the invention as first. This right is usually allocated for a short, defined period of time with confidentiality obligations.
 - e) Contractual background of R&D grants in the European Union's legislation
- 72. The Seventh Framework Program for Research and Technological Development is the main research financing tool of the EU, conducted in the period from 2007 until 2013. Through the framework programs (7th EC Framework Program, 7th EURATOM Framework Program, CIP) research activities of the highlighted priority fields get funding with the objective that the EU gains a leading position worldwide in these sectors. The direct or indirect objective of the framework programs is the funding of the creation of an IP of some kind and of its exploitation serving the common interest of society. The rules of participation in the FP7 are stated in the December 18, 2006 1906/2006/EC Parliament and Council Regulation on the actions of the FP7 (2007-2013) for companies, research centers and universities and on the rules for dissemination of research results.
- 73. The European Commission has adopted on the April 10, 2007 the general model grant agreement to be used in research projects funded under the FP7²⁷. The Commission proceeding in the name of the Community signs a contract with the beneficiaries according to a model grant agreement. The provisions stated in the model grant agreement regulate the

²⁷ http://cordis.europa.eu/fp7/calls-grant-agreement_en.html#standard_ga

²⁶ It is not a condition of the CRADA that the parties agree on the realization of a result. They can agree in such a way as well that the fee is also due in case the work is fulfilled without results.

legal relations between the Commission and the beneficiaries for the rights connected to the intellectual properties in harmony with the provisions of the relevant regulations. Considering the special terminology used in the FPs concerning the IPRs as well it seems reasonable to hereby give a short summary of the terms most often used.

- 74. The term background means the information at the disposal of the participants preceding their joining to the grant agreement and all copyrights and other intellectual properties connected to such information, which rights have been applied for by the participants preceding their joining to the grant agreement and which are necessary for performing the indirect activities or for using the results from the indirect activities. Compared to this, the term foreground means the results including information as well created due to the activities within the framework of the project independently from their patentability. Such results include rights connected to copyrights, design rights, patent rights, plant variety protection or similar protection types. Apart from the immaterial properties, the foreground includes the material results of the project as well (e.g. prototypes, microorganisms, etc.) The term of access right covers rights of licensing or other exploitation related to the background and the foreground, whilst dissemination means the appropriate publication of the foreground, excluding patent publication, however including the publication of the foreground in any media.
- 75. Besides defining the terms, the grant agreement governs the pre-existing rights or those created in the framework of the project. In case of background, participation in the project does not affect the ownership rights. The foreground originating from the activities of the project is by principle the property of the one who has created it. The European Community can become owner of the foreground in two cases: (i) coordination or granting activities aimed at the acquisition of products or services that fall under the public procurement procedure stated in the regulation of the budget; (ii) coordination or granting activities related to independent experts.
- According to the model grant agreement, if an employee or a person in other legal 76. relationship of any of the consortium members could be entitled to IPRs related to the foreground (e.g. student's relationship, people whose IP is not considered as a service invention), the concerned consortium member should ensure that these rights can be enjoyed in harmony with the obligations stated in the grant agreement. If the foreground is the result of a collaborative activity of several beneficiaries and the proportion of on each participant cannot be defined, the concerned parties will have common rights on this foreground. The beneficiaries can sign an agreement concerning the conditions of sharing and practice of these common rights. Without this a permissive regulation of the EU comes in force, that is each person having IPRs has the right to give a non-exclusive license agreement – with no sublicensing – with the following conditions: (a) all of the other IPRs owners must be formerly notified; (b) all of the other IPRs owners receive a realistic and fair offset. Together with the obligations (including access rights, dissemination) and formerly notifying the other participants, the foreground can be freely transferred. In case of a non-European third entity, this transfer can only take place with the former notification of the Commission (the Commission has veto rights).
- 77. If the foreground is suitable for industrial or commercial application, the owner must ensure its proper and efficient protection (but it is not compulsory to file a patent application, and it can be transferred to a third party). If there is no protection acquired, the Community may get the rights to acquire and maintain the protection. As to the dissemination, the

beneficiary should ensure that the disclosure of the foreground occurs as soon as possible. In case this is not happening, the Commission has the right of disclosure of the foreground. An additional rule on the dissemination is that it has to be in accordance with the protection of IPRs and the confidentiality agreements binding the parties, and the other concerned beneficiaries should be notified at least 45 days in advance (have objection rights). According to the regulation an access right can only be requested by any parties if it is necessary for the fulfillment of the project or for exploitation of their own foreground. The limits of the access rights are to be exactly defined.

- Questions concerning the protection of IPRs are advisable to be regulated both in the grant agreement and in the consortium agreement. The consortium agreement settles the internal legal relationship of the beneficiaries. If otherwise not regulated by the call for proposals, all participants of the project are obliged to sign a consortium agreement. The consortium agreement covers – among others – the following questions: i) the internal organization of the consortium; ii) the distribution of the Community financial contribution; iii) rules on dissemination, use and access rights, additional to those in Chapter III of the model grant agreement and to the provisions in the grant agreement; iv) the settlement of internal disputes including cases of abuse of power; v) liability, indemnification and confidentiality arrangements between the participants.
- Unlike the model agreement concerning the grant agreement, there is not one model agreement accepted by the Commission for the consortium agreements. Contents of the consortium agreement are defined by the consortium members themselves, but they cannot be against the grant agreement. However there are a few, non-official model agreements for those concerned. One of the most generally used model contracts is DESCA²⁸ (**DE**velopment of a Simplified Consortium Agreement for FP7). DESCA is a comprehensive, modular consortium agreement for the FP7. Initiated by key FP7 stakeholder groups, and codeveloped with the FP community, it offers a reliable frame of reference which seeks to balance the interests of all of the main participant categories in FP research projects: large and small companies, universities, public research institutes and RTOs. Another generally used model agreement is the IPCA (FP7 Integrated Projects Consortium Agreement). IPCA has been developed to facilitate the collaboration between the consortia members, by providing a reliable basis for the key European industrial R&D players when entering into agreements with their partners under the ICT theme of FP7. The contracting parties are guided by a table of comparison as well²⁹.
- Participants of the community FPs should also consider the regulations of their own national law as well as that of the other beneficiaries (consortium members). This is because the regulations of the national law apply for questions concerning the IPRs between the research institution and the researcher (service invention, professor's privilege, etc.). Furthermore, the community legislation over the framework programs may contain regulations against the national law (in Hungarian legislation, such an example is the conditions for licensing to third parties in case of joined ownership of rights). The community law in this case takes priority over the national law as a special rule.

²⁹ http://www.ipr-

 $^{^{28}\} http://www.desca-fp7.eu/$

Summary:

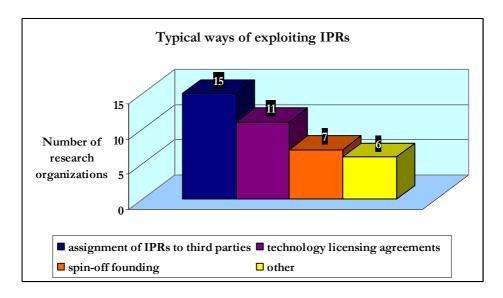
- 1. Apply a **uniform protocol** for the management of the CRADAs and grants received in consortium with industrial partners.
- 2. Since in the civil codes the ownership rights of the foreground are usually dispositively regulated, **include provisions** on IPRs from the CRADAS.
- 3. It is the task of the TTO to draft the contracts, review them and follow-up on their fulfillment.
- 4. In case of agreements related to grants especially if it is about multilateral agreements including foreign partners use uniform international standards, if possible the relevant model agreements of the EU.
- 5. As an annex to the agreements, **elaborate the list of the background** (pre-existing know-how) and make it part of the contract, otherwise it can be insecure what is the part of the development (foreground).

VI. THE TRANSFER OF TECHNOLOGY

A. General Issues, Technology Transfer Strategy

Facts: For most responding research organizations the assignment of IPRs is a usual way for the exploitation of the intellectual property. Compared to that, less research organizations sign licensing agreements, whilst one quarter of the responding research organizations do typically create spin-off companies (Figure 23).

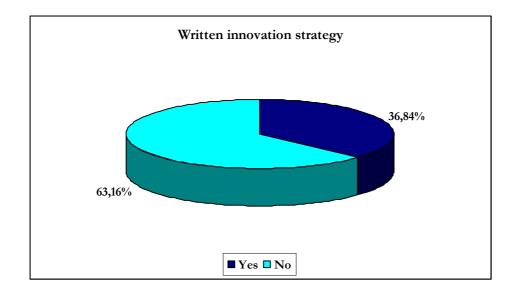
Figure 23: Typical ways of exploiting IPRs³⁰



81. Most responding research organizations (63,16%) do not have any internal written strategy on innovation (Figure 24).

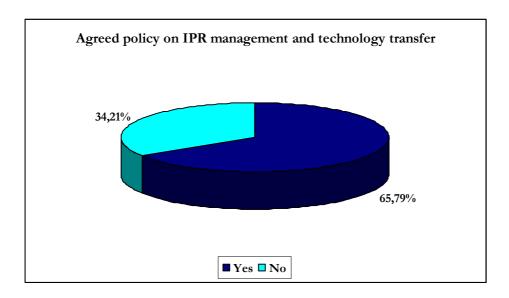
³⁰ Number of responding research organizations: 28.

Figure 24: Written innovation strategy³¹



82. However, approximately two-thirds (65,79%) of the research organizations do have a policy on the transfer of technology (Figure 25).

Figure 25: Agreed policy on IPRs management and technology transfer³²



a) Preparation of the TT strategy

83. Based on the type of technology and the accessible resources different business strategies are the most favorable. However, these different strategies are sometimes not compatible: for example if the establishment of a spin-off company is decided, it is important to keep the invention confidential as long as possible since due to disclosure, other companies having bigger resources may decide on developing and producing similar products. But if there is no spin-off company created, it may be reasonable to make sure that the technology is

³¹ Number of responding research organizations: 38.

³² Number of responding research organizations: 38.

disseminated in such wide circles that it reaches the potential licensees. Of course, if confidential information is transferred a non-disclosure agreement should be signed prior to sending the information. A strategic analysis identifying the full potential of the invention and the possible pitfalls could facilitate setting such deadlines that lead the project into realization as early as possible. This is called a technology transfer strategy.

b) Market analysis

- In order to define the commercial potential of a given technology it is necessary to have sufficient information on the product's potential market. To cover the expenses from IP protection and other significant costs, the product must target a large and fast growing market. It is also an important factor to be considered which segment of the market shall be targeted by the product (product family). This is because it is possible that the characteristics of the product only enable presence in a special niche of the market and only after a more thorough pre-analysis it may turn out that the product does unexpectedly stand apart from the other parts of the whole market. Penetration into the market is another important factor for forecasting the fate of the new product. In case the product is targeting an existing market, it has to compete with the competitor products, these are often only distinguished from the new product by their trademarks (e.g. market of personal vehicles, perfumes). In this case it is a question whether the consumers on the market are loyal to the trademarks they use or they would try out the competitor products as well? If there is no direct competition, we are talking about alternative products (which is actually not usual at all; an example is the market of research tools, that is when a certain task of measurement was not possible before but the new product is capable of it) and a plan should be elaborated using the data on the alternative products in order to enter the market.
- 85. It is important to know the laws of business competition: the competitors having large economic resources at their disposal can prevent the entrance of a new competitor into the market. Furthermore it is important to know about the competitor products and how these are related (positioned) to the newly developed product. Can this new product advance the former solutions with its price, its quality or with both? Can the new product compete even if the efforts of the competitors are taken into account?
 - c) The basic types of technology transfer strategies
- 86. The basic methods for exploiting the technologies based on a university's R&D are the following:
 - (i) Licensing to an established company,
 - (ii) Establishment of a spin-off company,
 - (iii) Assignment of the IPRs.

d) Licensing

- 87. With a few exceptions all technology transfers contain a licensing agreement, even in case of incorporation of a spin-off company. A license means the granting or transfer of rights to use an IPRs. Exploitation (in this tighter meaning) is sometimes the most favorable strategy for commercialization of a technology, since it has the following advantages³³:
 - (i) the expenses of product development and manufacturing are shared;
 - (ii) companies that have been present on the market for a longer time have well developed market channels for selling the product;
 - (iii) the technology can appear as an improvement of the knowledge basis existing at the licensee;
 - (iv) an experienced management significantly raises the chance for successful introduction of the product;
 - (v) the licensor still owns the IPRs and receives income from it, usually in royalty;
 - (vi) licensing-out also helps commercialization of the technology and reaching new markets that are otherwise inaccessible;
 - (vii) licensing also makes it possible to settle IP disputes by turning opponents into partners instead of a long and costly lawsuit;
- (viii) licensing also helps controlling innovations and the direction and evolution of technologies;
 - (ix) a licensing agreement giving access to innovative technologies can enable an enterprise to reach the market faster;
 - (x) through licensing, a company with no opportunity for research and development can also access technical advances necessary for improved products;
 - (xi) some licensing-in opportunities, together with the company's current technology portfolio can lead to new products and opportunities.
 - e) Spin-off companies
- 88. Sometimes a decision is made that a new company is to be created with the view of commercialization of the new technology and the IPRs is transferred (very often licensed) to it. A spin-off company is more successful with the following conditions:
 - (i) a clean platform technology possessing diverse possibilities of application with several promising products in the pipeline;
 - (ii) easily accessible market without significant competitors (creating the market or a niche);
 - (iii) strong patent protection;
 - (iv) commitment of the inventors
 - (v) A competent management team.

Reference: Exchanging Value – Negotiating Technology Licensing Agreements, WIPO, 2005,p. 19.

f) Realization of the technology transfer strategy

89. If a technology has been developed to satisfy a special need identified up by an industrial partner, it is called a technology pull. If an external partner is sought for the technology formerly developed by the university, the process is called technology push. In countries in transition technology push is a common necessity as a result of the absence of an established business community.

g) Technology push

In order to find a partner willing to exploit a special technology the proper information should be published in a way which can attract attention. It is, however, important that not too much information should be disclosed about the technology, even if a patent application has already been filed. To enforce IP rights against a large company is a very expensive and sometimes even impossible task. Thus only limited information should be published and, if possible, no discussion should take place without a confidentiality agreement. Typically the same information is disclosed to several partners. If every time a separate document was elaborated that would be an extreme waste of energy. Therefore to solve this problem an information sheet can be prepared that is a short description of the technology without any confidential information. This way the technology information sheet becomes a tool for communication. One should consult with the inventor so that no confidential information can be leaked even by accident and that the data disclosed is up to date and realistic. If the potential types of partners have been identified in the technology transfer strategy, that could be used for creating the list of potential partners with whom contact can be taken up by a personal call for collaboration. One very useful source for finding the potential partners is a market analysis report on the given special field.

h) Technology pull

91. In case a need for technology is raised from industry, the industrial player finds the academic partner. In such cases they usually sign a CRADA (see above) and the results from development are transferred to the industrial partner which will then build it into its new products. In these cases there is no need to find an industrial partner for the technology and the tasks of the technology manager come down to ensuring the reputation of the university for research and to carefully draft the CRADA and to follow-up its realization.

Figure 26: An exemplary technology transfer service timeline for a technology transfer professional

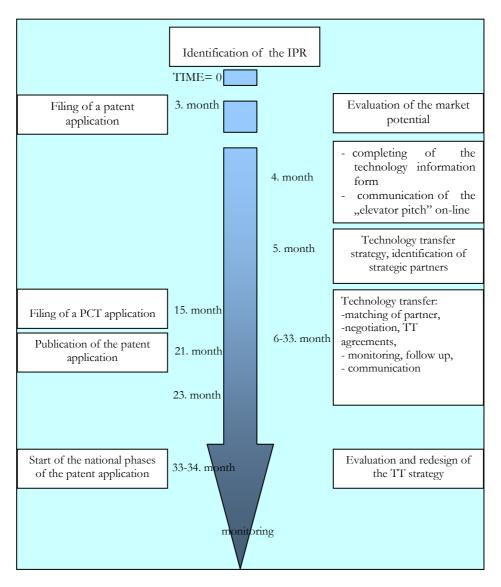


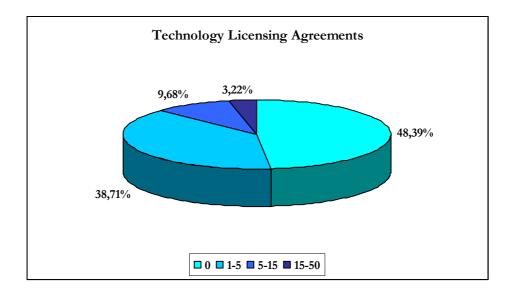
Figure 27: An exemplary timeline for making technology transfer decisions

<u>Activity</u>	<u>Deadline</u>	<u>Decision</u>
First intermises		<u>point</u>
First interview Initial avaluation of the commercial potential & the	2 weeks after 1 st	
Initial evaluation of the commercial potential & the patentability of the invention if necessary complete	communication (FC)	Yes
	communication (FC)	
innovation client and project datasheets		
Invention declaration		
If necessary notify the responsible for innovation	2 weeks after FC	No
management in the inventor's organization, find the financial sources that will cover the TT	2 weeks after FC	No
management		
In depth interview with inventor In this interview further information is gethered on		
In this interview further information is gathered on	3 weeks after FC	No
the new technology. Fill in the invention		
description datasheet.		
Prior art research Analysis of the natest literature to determine the	5 weeks after FC	NT.
Analysis of the patent literature to determine the	5 weeks after FC	No
novelty and innovativeness		
Technology assessment questionnaire		
Evaluation of the patentability, determine the best	6 weeks after FC	Yes
fitting TT strategy and the risk position of the		
technology		
Contact patent attorney		N. T
Determine which patent attorney best fits the	6 weeks after FC	No
technology and make first contact		
TT strategy sheet	10 1 6 FG	N. T
Gives a condensed planning for the technology	10 weeks after FC	No
transfer		
National patent application	12 weeks after FC	No
Performed by patent attorney		
Technology info sheet	14 1 6 FG	NT
Standardized sheet with non-confidential	14 weeks after FC	No
information		
Technology push	14 1 6 FC	NT
Publish information on TT networks; if no spin off	14 weeks after FC	No
will be formed send out invitation for collaboration		
International patent application through PCT		
Performed by patent attorney, if no licensee found	15 months after FC	Yes
and no grants available, no international patent		
application		
Evaluation	16 manufactor FC	NT
Evaluation of the technology transfer both	16 months after FC	No
internally and by the client		
Follow up		
Additional consulting services to keep the	21 months after FC, yearly	Yes
innovation on track and follow up on the milestones	ow up on the innestones afterwards	
in the license agreement (find new licensee or		
renegotiate if milestones not met)		

B. Technology Licensing Agreements

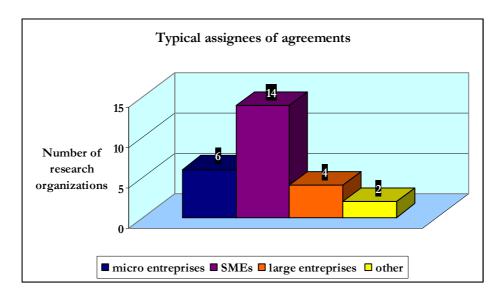
Facts: Of the responding research organizations the majority only makes a limited number of licensing agreements. In only one research organization there were annually more than 15 such agreements (Figure 28).

Figure 28: Technology licensing agreements³⁴



92. It is characteristic for all responding research organizations, that they make licensing agreements with SMEs. In contrast licensing agreements made with large enterprises are much less common: only four research organizations checked large enterprises as typical partners. A minor portion of the responding research organizations also makes license agreements with institutions other than enterprises.

Figure 29: Typical assignees of agreements³⁵



³⁴ Number of responding research organizations: 31.

³⁵ Number of responding research organizations: 16.

- a) About licensing in general
- 93. Licensing takes place when a licensor is in possession of a knowledge or information (IPRs, most often of technical nature) that carries business value, furthermore, the licensor possesses the exclusive right to transfer the IPRs to the licensee for commercialization. The aim of the licensing agreement is the transfer of the information in question, and the utilization of it by the licensee. The licensing agreement obliges the licensor to make it possible for the licensee to practice and use a specified technical solution, in a specified quality optionally under specified trademarks. In order to ensure this the licensor will transfer the required information and legal authorization to the licensee; the licensee is obliged to pay licensing fee. According to UNICO Practical Guidelines: "An IP license is a contract under which an owner of the IP (the licensor) permits another person (the licensee) to engage in activities that, in the absence of the license, would infringe the licensor's legal rights attached to the IP." Here we note, licensing is not a transfer of right; it is a consent to the other party to use the IPRs under certain conditions.
- 94. In order to successfully complete a licensing deal it is necessary to thoroughly prepare and conduct negotiation(s), elaborate and finally sign the licensing agreement according to the steps below:
- (a) Preparation
 - (i) evaluate the intellectual property that will be licensed out;
 - (ii) define the aim of the license (formulation of the goal to be reached and the expected benefits)
 - (iii) define the type of license (combined, simple);
 - (iv) plan the contents, scope, and duration of the license;
 - (v) collect, prepare the data and documents connected to the IP that will be licensed (e.g. patent documents, preliminary research reports if available, the responses of other potential licensees, etc.)
- (b) License negotiation
 - (i) prepare for the negotiation (specify the questions that need to be answered during the negotiation, elaborate a negotiation strategy considering the interests of the other party and determine in advance possible compromises that will be needed to reach the desired aim; determine who will be taking part in the negotiations, determine the tasks and the mandate of the participating delegates);
 - (ii) conduct the negotiation;
 - (iii) evaluate the negotiation, determine and propose a possible counter offer.
- (c) Elaboration of license agreement draft
 - (i) formulate the draft in writing;
 - (ii) submit the draft for review;
 - (iii) obtain and assemble the annexes of the licensing agreement;
 - (iv) finalize the licensing agreement after the approval of both sides.
- (d) Conclusion of the licensing agreement (signing), registration.

Figure 30: Stages of a licensing deal

Preparation	Negotiation	Elaboration of the contract	Signing the contract and registration
Evaluation of the intellectual property	Preparation	Formulation of the text	Signing
Definition of the aim of the license	Conducting	Review	Registration in the register of a competent authority
Definition of the license type	Evaluation	Annexes	
Definition of the extent and subject of the license		Finalization	
Structuring the data and information			

b) Types of licenses

- 95. License agreements can be defined as a group of contracts that incorporates several types of contract subtypes with specific features. The types of license agreements can be grouped according to the rights of the licensee, the subject, territorial scope and exclusivity of the license and the permission for further exploitation (sub-license).
- 96. On the basis of the subject of the licensing agreement basically three practically four types of agreements can be distinguished. We note, the classification is not tight, depending from the nature of the transferred information, the features of all types can appear in one licensing agreement. The first type is the conventional patent licensing agreement. The second type is the agreement for supplying know-how. The third type can be the trademark license agreement, in which technical aspects only have an indirect role. The most common type is the fourth: the mixed (hybrid) license agreement that usually incorporates the first two variants (patented invention and know-how). Other kind of classification is also possible.
- 97. Beyond the classification, on the basis of the properties of the contract's subject licensing agreements can be grouped by other aspects: the differentiation can be made according to the permitted range of utilization for the licensee e.g. the licensee is authorized to only produce and use the product, is granted the right to market it as well, or may use the technical solution in question only for a narrow range of possible applications.
- 98. Agreements can also be distinguished by the territorial scope for their utilization. The utilization rights of the licensee can be limited to one single country, region of a country or can be extended to multiple countries. The usual division between exclusive and non-exclusive licenses is partially based on the latter arrangement. In case of a non-exclusive license the licensee may utilize the subjected technical solution according to the conditions of the agreement –, but the licensor keeps the right for utilization and can enter into a license agreement of the same subject with a third party. In case of exclusive licenses the licensor may not grant permission for third parties in the area of the specified country except for the licensee and may not exploit the invention themselves. Under a sole license the licensor may utilize the solution in question (or sometimes even be obliged to further develop or improve it). Obviously there is a difference between the licensing fees of the exclusive, sole, and the non-exclusive licensing agreements.

99. Finally sub-licenses need to be mentioned that allow the licensee to extend licenses in the subject of the original licensing agreement. This is common especially for exclusive or sole licenses.

Figure 31: Types of license agreements

		Patent license agreement
1.	1 Subject of ligance	Know-how license agreement
1.	Subject of license	Mixed (Hybrid) license agreement
		Trademark license agreement
		Production/manufacture and usage
		Marketing/distribution
2.	Utilization rights of licensee	Production/manufacture and usage and marketing/distribution
		Narrower scope of possible utilization
3.	Territorial scope of	One country or one region of a country
3.	utilization	Multiple countries
		Non-exclusive (licensor, licensee or additional licensee may utilize)
4.	Exclusivity of license	Exclusive (only licensee may utilize)
		Sole (only licensee may utilize, licensor or third party may not)
		Present (licensee may grant permission for further
5.	5. Possibility for sub-licenses	utilization)
	2 obbliding for ball freeinges	Not present (licensee may not grant permission for
		further utilization)

c) Terms, concepts used in license agreements

100. It is the interest of both parties to specify the terms and concepts used during the licensing agreement explicitly and correctly. Clear definitions accepted by both parties may prevent misunderstandings during the application and performance of the license agreement. In case of debate none of the parties will be able to call upon misunderstandings of one or another term, and possibly ill intentioned parties later will find it hard to prove or bring into doubt the circumstances that were or seemed unambiguous during the signing of the agreement. The definition of basic terms is even more important for licensing agreements because of their immaterial character.

101. The basic terms in licensing agreements can be defined in two ways: in case of "simpler" deals where no problems are expected this can happen according to their generally accepted meaning. For complicated cases however – for example when other agreements of the same IP are affected – this can happen in an agreement specific way. The method to be used to determine the definitions in the agreement can be chosen depending on the circumstances of the specific deal.

Figure 32: Basic terms

Subject of the license/ transferred technology	Patent, know-how (can be written down), description of other IP	
Effect of license	For which territory, for what time and for what subject is the license valid?	
Utilization, development	What rights will the licensee own?	
Type of license (non-exclusive, exclusive, solitary)	Who is permitted to utilize at a given time? (licensor, licensee, third party after the licenser's permission)	
Extent of utilization rights	Limited or unlimited	
Licensing fee	upfront "milestones", royalty, coverage proportion, royalty base, royalty rate	
Sub-license	Is licensee allowed to grant permission for further utilization?	

- d) The subject of the license / the transferred technology
- 102. It is very important to determine the subject of the license / the transferred technology (depending on the type of license this can be a patent / patent application, know-how, trademark or other IP).
- 103. The subject can be determined by the inclusion of the title and number of the patent application. In case the IP has been patented or in case the patenting prosecution has been started, it is recommended to attach the referred patent descriptions as annexes in order to unambiguously determine and interpret professional technical expressions connected to the subject of the license in a uniform way.
- 104. If know-how is transferred in the license deal, it is essential to determine the clear and exact content of the licensed know-how. A technical documentation or figure can be attached to define a describable or objectified know-how, in which the applied raw materials manufacturing procedures, manufactured products and design of the products should be specified. Non-describable or HR-based know-how can be added in a separate technical assistance agreement or clause incorporated in the license agreement. Technical assistance means here the education required for the installation and the maintenance of the licensed technology, including provision of schemes, descriptions, operation procedures and guidelines.
 - e) Effect of the license (territory, subject and term)
- 105. The territorial scope of a license is the geographic area in which the licensor permits the utilization of the invention by the licensee. It is advisable that the territorial scope of the license coincides with the scope of already existing (granted) patents. If the IPRs is in patent application phase and the licensing takes place prior to granting the patents, it seems to be useful to specify the value of given territory contributing to the licensing fee. Otherwise if the licensor (patent applicant) fails to receive patent protection for the licensed IPRS, the licensee may refer to this fact and challenge the IPRs original economic value.

- 106. The subject matter of the license is related with the definition of the patent scope, which is in turn defined by the claims of the patent description. The claims are to be understood in the light of the description and the figures; in other words the scope of the patent is defined only by the technical information included in the claims. When the patented invention is about several products, processes and applications, it is essential to define and limit the scope that is necessary for the licensee to use the technology. If the exploitation is authorized for the full scope, the licensed scope does not have to be defined. (If several separate IPRs are authorized, these should be separated exactly also in light of the conditions for license fee payment).
- 107. The term of the license is the time span within which the licensor permits the utilization of the innovation by the licensee. Generally the licensing agreement comes into effect on the day it is signed and remains in effect until a date defined by the license agreement. In the case of patent license agreements the length of the agreement cannot exceed the duration of the patent protection. The duration of the license can be decided taking into account the value, development level and marketability of the IP; the aim of the license (e.g. the university intends to grant long term utilization rights to a university spin-off, or wishes to grant permission to other industrial partners in mid-term); and other aspects of the agreement of the parties.
- 108. Often the subject matter of the agreement is not a granted patent at the time of signature. So even though the invention is the subject matter of the license, until the day patent is granted it is the rights sought by the patent application that we are actually transferring.
 - f) Terms relating to the subject matter of the license (rights for utilization and development)
- 109. The content of a specific legal relationship is determined by the rights and obligations of the parties. It is recommended to define the utilization and development terms already during the preparation and negotiation, and then later during the formulation of the licensing agreement include them in the rights of the licensee.

110. Utilization can cover:

- (i) manufacturing, usage and marketing of the invention, or
- (ii) offering the product that is the subject of the invention for marketing, holding it on stock or importing it for that purpose;
- (iii) usage of the method according to the invention, or offering the method for usage;
- (iv) manufacturing, usage, marketing of products directly on the basis of the method according to the invention, offering it for marketing, or holding it on stock or importing it for the same purpose.
- 111. It may occur that instead of granting all rights the licensor grants the rights only for manufacturing/production, or only for utilization/application and optionally for related further developments (in this case the license agreement already contains the elements of a research agreement and the legal relationship should be regulated accordingly) or only for distribution/sales. In these cases it is recommended to define these terms as well in the contract.

- 112. Development of the subject of the license is of special significance in licensing deals. Development means such improvement that brings a substantial difference to the technical description present in the contract; the development is not necessarily of such extent that the developed product, process, application or instrument would be patentable on its own. The licensee is only authorized to exploit the results of the development (that is the scope of the license agreement is extended to the results of development automatically). Regulations related to the foreground need special attention. The rights related to the development by the licensee are owned by the licensee. As to the IP being the subject of development, the contract can state that the parties not offending the rules on fair competition, either in the license agreement or in a separate agreement grant a so-called cross-license to each other (that is the licensee ensures the non-exclusive exploitation of the IP/product being developed by him to the licensor and the licensor undertakes to ensure the same to the licensee on his own developments). If both parties substantially contribute to the development, a joint patent application/patent can be created.
 - g) Terms related to the scope of the granted rights
- 113. It is important to clarify at the beginning of a licensing agreement the definition of the terms:
 - exclusive (only the licensee or a third party authorized by him is allowed to utilize the invention);
 sole (besides of the licensee the licensor is allowed to utilize the invention, the licensee is not allowed to grant utilization rights to third parties);
 - (ii) non-exclusive (the licensee and the licensor are allowed to utilize the invention, and the licensor may grant utilization rights to third parties); and
 - (iii) sub-license (the licensee allows third parties to utilize the invention).
- 114. Depending on the circumstances of the deal the licensor should carefully consider whether to transfer the utilization rights with or without restrictions to the licensee. In practice four types of restrictions are known:
 - (i) territorial restriction: limit the utilization rights to a smaller area than that of the patent application/covers;
 - (ii) application restriction: limit the use of the invention to one or more but not all of the purposes known at the signing of the agreement;
 - (iii) quantity restriction: restrict the release quantity of the product that is the subject of the invention:
 - (iv) quality minimum requirements: minimum requirements for the technical parameters of the product released during the realization of the invention.
- 115. Considering especially the subject matter of the license, its stage of development and its objectives as well as the expected income, it is recommended to think of the possibility or the necessity of restrictions. Much depends on the objective of the license, for instance in case of a university spin-off it is reasonable to extend a long-term license free of restrictions that grants the widest possible mandate to the spin-off; on the other hand if the interest of several industrial partners may be expected for the exploitation of an IP of large market potential or in case the licensor grants licenses to several partners then the use of restrictions should definitely be considered. To improve income it should be considered to use restrictions if a favorable exploitation opportunity is expected in a relatively short period of time.

116. If the licensor intends to provide several licenses parallely to different licensees it is essential to exactly define the scope of the licenses – especially the territorial and application scope – taking into consideration exclusivity and sub-licensing. (We stress here that the delimitation of the objective of application and the definition of the level of restrictions can only happen with the involvement of the inventor who has excellent knowledge of the IPRs. Only he can exactly define the different applications or objectives with appropriate professionalism). This is the only way that overlapping exploitation rights of the different licensees and future legal disputes can be avoided.

h) The licensing fee

- 117. The licensing fee is the financial compensation for the exploitation right that the licensee has to pay. Numerous variants of the licensing fee are known and used in the licensing practice, but in all cases the parties should try to elaborate and include into the contract a payment method that most suits the circumstances of the agreement, the nature of the license and the other contractual conditions defined by the parties.
- 118. We can differentiate between two basic types of license fees (that often appear together in one contract). The first type is lump sum license fees paid following a so called milestone event. This group for example includes: lump sums to be paid when signing the contract; time-based payments to be paid every nth year after the signing of the contract; milestones to be paid on market release; sums to be paid when different levels of development have been reached (commonly used especially in the pharmaceutical industry); sums to be paid when the licensee's rights are extended (e.g. as a result of further developments). The second type are royalties (by definition: a sum defined as a percentage of the royalty basis, this is to be paid to the licensor when products or services derived from the invention are sold).

Figure 33: Types of license fees

UPFRONT	In a lump sum upon the signing of the contract	
MILESTONES	In a lump sum when achieving development milestones	
	% calculated from the income	
ROYALTY	Royalty basis	Royalty rate
KUIALII	Net or Gross sales price multiplied	Percentage, dependent on object of
	with the coverage	the license

- 119. Royalty consists of two components: the royalty basis and the royalty rate. The royalty basis could be the production cost or the profit from sales (rarely used since this is rather sensitive data and disclosing it to the other party may harm the interest of confidentiality of the licensee, which in turn may result in unnecessary disputes). It could be a fixed unit sum of income from the sales of the licensed product; or most often it is the gross or net income from sales. It must be mentioned that if the royalty basis is defined as the net sales income, there may be practical problems and eventually disputes when doing the calculations since it is necessary to verify the deductible costs. In order to avoid this, the gross sales income can be applied as royalty basis, this simplifies the calculation.
- 120. The other component of the royalty is the royalty rate (a defined percentage of the royalty basis). When defining this, it is important to make the licensing a win-win transaction (a too low or too high licensing fee may cause one of the parties to lose their interest or the motivation for the transaction may be reduced.)

- 121. The term coverage is used in this context to indicate the proportion expressed with a number between 0 and 1 of the value represented by the IP (subject matter of the licensing agreement) within the product or service. If the invention is suitable for exploitation/sales, the coverage is one. If the licensee is authorized by license agreement to sell the developed product as well then the coverage may change and it is advisable to state the relevant provisions in the contract.
- 122. In case of exclusive licensing agreements there is often a minimum licensing fee that is a minimum obligatory effort imposed on the licensee. The licensing fee according to this minimum licensing fee payment obligation is to be paid independent of the production rate or the amount of profit (best effort's clause).

Figure 34: Checklist of items to be clarified before the license transfer

Subject matter	Patent ID: □
	Know-how ID: □
	Mix (patent + know-how) ID: \Box
	Software ID: □
	Trademark ID: □
	Other ID:
Exclusivity	Non-exclusive □
-	Exclusive
	Sole □
Cross-licensing	Yes 🗆
	No □
Specification of licensing	Full exploitation rights □
rights	Only exploitation/application \square
	Only manufacturing/Production □
	Only distribution/Marketing □
Territorial scope	For full patented territory
	For defined countries
	Which countries? □
	Region
Term	Until the expiry of patent protection \square
	A defined period of years □
Restrictions on the license/	Unlimited □
What is the extent of the	Territorial restrictions □
license?	Restriction based on application □
	Restrictions on quantity □
	Quality requirements
Bearing the costs of	Licensor □
patenting prosecution,	Licensee
maintenance the patent and	Licensee 🗆
other costs	
Sub-licensing	Yes □
	No □
Licensing fee	Upfront □
	Milestones□
	Royalty □
	Costs of maintenance, patenting costs built-in □

123. Below you will find summarized the basic terms and conditions of a licensing agreement in the medical industry.

Figure 35: Summarized the basic terms and conditions of a licensing agreement in the medical industry

	Licensor: university spin-off company,	
The partners	Licensee: middle sized pharmaceutical	
	company.	
	A patented medical device; know-how and	
The subject matter of the transfer	technical assistance not included. Innovation	
(licensed technology)	phase: proof of concept. Background	
	/foreground IPRs.	
Exclusivity	Exclusive	
Territorial scope	Full patented territory.	
Specification of the licensed rights	Manufacturing with no restrictions on quantity	
Specification of the ficensed rights	but with minimum quality requirements.	
Sublicensing	Granted with reach through clause	
	1. Upfront: NO,	
Licensing for	2. Milestones payment: NO,	
Licensing fee	3. Royalty: less than 5% of the wholesales	
	price of the product.	
Research collaboration	If yes, then cross-licensing for the	
Research conaboration	improvement.	

i) Structure of the license agreement

124. Experience learns that it is crucial to define the content of a licensing agreement in great detail, especially if one of the contracting parties is in a weaker position. It is required by good faith, however, that the licensor and licensee both assume that the other party will take the responsibility to fulfill the rights and commitments as described in the license agreement – regardless of their negotiation positions. The provisions of the licensing agreement can be – among many other systems –as follows. In this case these are also the chapters of the license agreement.

Figure 36: Structure of a license agreement

- a) background of contract, definition of basic terms
- b) subject and terms of the licensing agreement
- c) duration of contract, termination;
- d) rights and obligations of licensor;
- e) rights and obligations of licensee;
- f) issues regulated by the technical assistance contract;
- g) due diligence
- h) guarantee, warranty
- i) confidentiality, references
- i) contacts
- k) other provisions

125. When using the above structure, it is possible to rely on the information from the appropriately filled in checklist. However, as we already mentioned the use of templates should be avoided.

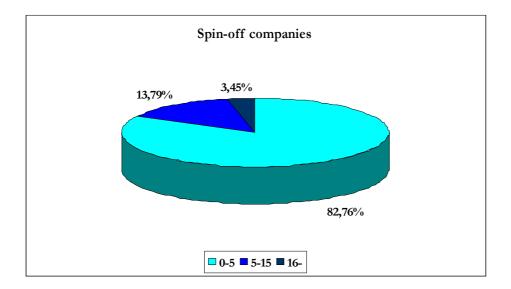
Summary:

- 1. Elaborate a uniform protocol for licensing agreement management.
- 2. Instead of completing contract templates, keep to the practice of preparing, negotiating and drafting the licensing agreement.
- 3. Use a checklist for license management.
- 4. It is the task of the TTO to elaborate, review, and track fulfillment of license agreements.
- 5. Make sure that the payment conditions are clear and result in a win-win situation for both parties and that the warranty loaded on the academic partner is reasonably restricted.

C. Early stage innovation from the SME point of view: management of spin-offs

Facts: The number of spin-off companies founded in the past two years, by majority of the responding research organizations was maximum 5 (Figure 37). The majority of the responding research organizations do not take equity in the spin-off companies that utilize their research results (Figure 38). Three-forth of the researchers keep their share in the spin-off company for more than two years (Figure 39). The universities usually give a non-monetary contribution to the companies (Figure 40). For the majority of the responding research organizations (62,5%), the researcher creating the IP is involved in the spin-off company neither as owner, nor as employee (Figure 41). The majority of the research organizations (64,52%) does not provide incubation services for spin-offs (Figure 42).

Figure 37: Spin-off companies³⁶



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³⁶ Number of responding research organizations: 29.

Figure 38: Share in spin-off company³⁷

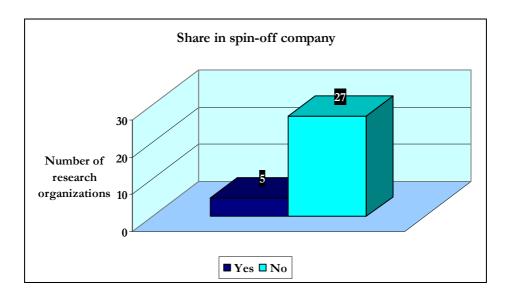


Figure 39: Share in the spin-off company³⁸



Number of responding research organizations: 32.
 Number of responding research organizations: 4.

Figure 40: Providing of contribution in cash to the share capital of the spin-off company³⁹

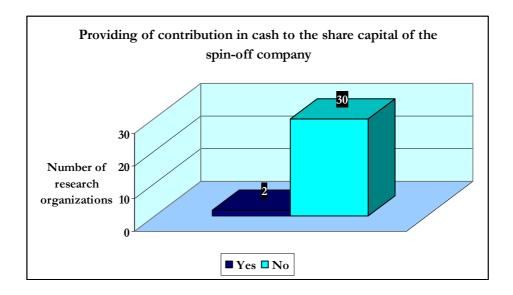
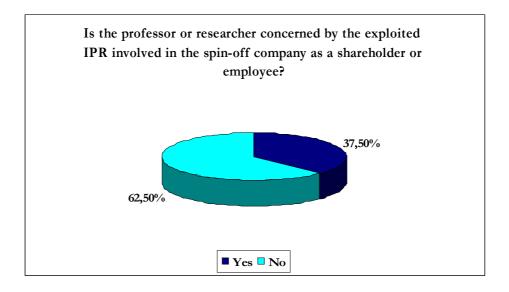
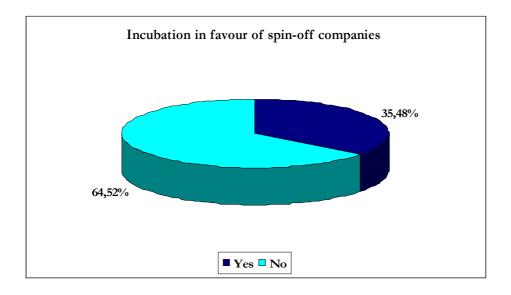


Figure 41: Is the professor or researcher concerned with the exploited IPRS involved in the spin-off company as a shareholder or employee?⁴⁰



Number of responding research organizations: 32.
 Number of responding research organizations: 32.

Figure 42: Incubation in favor of spin-off companies⁴¹



a) What do we call a university spin-off?

126. A university spin-off is any project in which a company is founded in order to utilize university technology in the framework of a separate company. A conventional university spin-off company is created by scientists of the university to exploit an IP that was created in and is owned by the university. According to the definition by the OECD, the founders of the spin-off company can be former employees of the university. University spin-offs can also be companies that were founded by people totally independent of the research organization in order to exploit the technology licensed from the research organization (Figure 43).

Figure 43: University spin-off according to OECD

University spin-off according to OECD			
Strict interpretation		In a wider sense	
University is founder	University receives equity	Company founded by university researcher	Independent start-up
contribution in kind of IP + optional monetary contribution		the IPRS	is licensed

⁴¹ Number of responding research organizations: 31.

b) Issues to be clarified before a spin-off incorporation

Business aspects

127. The possible commercial utilization alternatives should be evaluated, weighing their risk factors against their potential positive effects. The most commonly examined risk factors are: market risk, technical risk, economic risk and management/human resources risk. The spin-off has to be assessed, and the examiner should give a correct estimation of the significance of the arising risks for each alternative.

Figure 44: Risk assessment⁴²

Risk level	Marketing	Technical	Economic	Management
Low	 Product validated by several lead clients; Large confirmed target market; Buyer readiness confirmed; 	Working production prototype;Reliability established;Meets regulatory requirements;	 Validated investor interest in providing needed seed capital or can be funded from operations (bootstrapped); Timely opportunity for investors; 	- Most CXO positions filled with experienced executives with successful track records in start-ups;
Medium	 Modest or incomplete product validation; Several target markets; Traction needed in several target markets to make the opportunity large enough; 	 Working preproduction prototype; Technical challenges almost entirely limited to scale up or manufacturability; 	 Investors show interest but may want to syndicate owing to perceived risk and/or size of investment; Early on timing; 	 Experienced and successful CEO but gaps remain in other key positions; Likelihood of filling other management positions is good;
High	 Little or no product validation, perhaps only concept; Target markets developing and unsure of size; 	 Lab prototype just meets criteria for proof of concept; Foresee engineering challenges to produce a prototype; 	 Little or no investor interest; Timing not optimal; Requires substantial capital; 	 Little experience within current management team; Likelihood of filling management positions is poor until the opportunity is funded and/or becomes more attractive/compelling.

128. The assessment of the risk level alone is not enough to make an initial decision. The assessment should estimate the consequences of each alternative. Obviously the decision is easiest in case of a minor risk coupled with a major opportunity. The decision making tool depends on many factors. Different individuals and legal entities feel, measure and tolerate risk completely differently. Therefore it is hard to elaborate a consistent and systematic evaluation system.

Reference: Clement J. Langemeyer: When do start-ups make sense? Journal of the Association of University Technology Managers, Fall 2004

Legal aspects

129. From the economical and legal point of view the foundation of a spin-off company is the same as that of any other company. Therefore the general considerations about incorporation, syndication and the potential related agreements should be taken into consideration. Below a checklist is given that contains the practical and legal issues related to the foundation of a spin-off.

Figure 45: Legal issues of strategic importance to be clarified before spin-off incorporation

Will the university be a shareholder of the company?	Yes □
	No 🗆
How can the IPRS be transferred?	Contribution in kind □
	Licensing 🗆
What resources are to be used?	Grant □
	Loan 🗆
	Venture capital □
	Private investor □
	Other 🗆
Do the partners want to create a syndicate agreement with	Yes □
each other?	No 🗆
Does the spin-off plan activities/development that requires	Yes □
collaboration or a cooperation agreement with the	No 🗆
university?	
Does the university want an option that ensures potential	Yes □
share acquisition in the future?	No 🗆
If the University is involved as a member, what is its exit	Option 🗆
strategy?	Other \square
Do the investors have an exit strategy	Yes
	No

130. Below you will find two examples for typical university spin-offs.

Figure 46: Two examples for typical university spin-offs

Feature	Plantacosmetics Ltd.	CE Optics Ltd.
Ownership structure	 Biological Research Center, Hungarian Academy of Sciences: 25% Inventors: 60% Business angel: 15% 	 University of Szeged: 0% Inventors: 100%
The project	A cosmetic formulation using a novel, patented protein, which reacts with the aggressive aldehydes eliminating them from the skin cell. Both clinical and cosmetical application are possible. The detoxication effects of the product slows down the ageing of the skin and helps eliminate the adverse effects of the environmental stress (sunshine).	A laser technology includes a novel, protected setup and method to detect physical, chemical and biological processes that take place on the atto and femtosecond time scale. The system is simpler than the state of the art technologies.
Owner of the commercialized IPRs	 Biological Research Center, Hungarian Academy of Sciences; Inventors; Business angel; 	University of Szeged
Transfer of IPRs	Licensing in	Licensing in
Option rights for the university	-	No
Syndicate agreement with the IPR owner	Yes	No
Research collaboration with the original IPRs owner	Yes	Yes
Location of the spin-off product development activities	BRC laboratories	University laboratories
Comparative advantage of the project/reasons for the establishment of a spin-off	 Novel, patented active compound, Skin impairment molecules can be directly removed. 	 Simplifical product as compared to the state of the art, Cost effective technological solution.
Objectives of the partners	 Joint product development with an industrial partner, Licensing out of the technology, Buy-out of the spin-off. 	 Joint venture with an industrial partner, Up-scaling or alternatively, Licensing out of the technology.

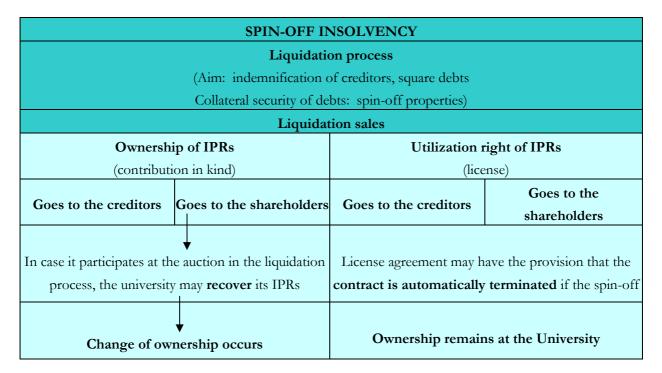
- 131. Additional information about the spin-offs and the best practices in the field can be found in University spin-offs in Europe- Overview and good practice (European Commission, 2002).
- 132. In the following the IPRs transfer strategy is highlighted as one of the strategical issues of legal importance that needs to be clarified before the spin-off company is founded. The spin-off company can acquire IPRs in principle in two ways: contribution in kind or licensing. The two methods have the following differences:

Figure 47: Acquisition of IP by a spin-off company

Contribution in kind	License	
(IPRs = contribution in kind)	(IPRs = subject of a license agreement)	
Transfer at spin-off foundation	Transfer after foundation,	
	the spin-off already exists when it becomes a licensee	
Methods of transfer defined by the corporate agreement	Methods of transfer defined by the licensing	
and the Corporate Law	agreement	
IP becomes property of the spin-off	IP remains property of the university, the right for	
	exploitation is transferred to the spin-off company	
IP as contribution in kind is part of the capital	Exploitation rights are assets listed in the balance	
	sheets	
Value of contribution in kind is defined by the partners,	Value of the license is defined by the partners in the	
but the provider is liable for the value	licensing agreement, it can be amended	
Regulations on corporate proceedings apply, company	Private contract, known only to the partners,	
registration, public domain	confidentiality clauses applied, non-public domain	
Decreasing value of the IPRs	Decreasing value of the IPRs affects the license	
affects the capital,	agreement (can be a reason for contract	
even the existence of the spin-off company may be at	modification or termination), but does not affect the	
risk	spin-off's capital or existence	

- 133. To sum up the above: if the IPRs are a contribution in kind, it becomes a part of the nominal capital and an integral part of the company. As a result changes in the value of IPRs affect the company and changes in the company's legal situation can have effects on the legal status of the IPRs. The liquidation or termination of the company can result in changes in the IPRs ownership. Figure 48 is a summary of these cases.
- 134. When a spin-off company goes bankrupt, it is liquidated. Once liquidation starts, the liquidator becomes the trustee of the company and the owners loose their rights over the company. The partners can no longer decide over the future of the company's assets and the liquidator sells the assets in a tender or auction.
- 135. Since both the IPRs and the rights for its utilization are part of the spin-off company's assets, they can become as a result of liquidation the property of third parties. This way it is possible that a member of the spin-off might regain the IP in the liquidation procedure.

Figure 48: Effects of spin-off insolvency on the IPRs



- 136. If IPRs are given as a contribution in kind, any change in status of the IPRs or their value affects the spin-off. The possible consequences are summoned in Figure 49. The commercial value of the IPRs depends on many factors: most important of course is the legal protection status, the form of protection (patent, utility model, etc.) and its scope (claims, territorial scope, period of protection).
- 137. The utilization and commercialization of a technology is time dependant process. During this time, changes can take place that affect the commercial value of the IPRs, for example the patent can be nullified, the protection time can expire, development can fail or be successful. If the commercialization occurs within the spin-off company, these circumstances obviously will affect the company and the exact nature of the consequences will be different if the IPRs was transferred to the spin-off's through contribution in kind or through a license agreement.

Figure 49: Effect of changes in the IPRs value on the spin-off company

Change of intellectual property value			
Ownership of intellectual value		Exploitation rights over the IPRs	
(contribution in kind)		(license)	
The nominal capital cannot become less than the		Represented in the balance sheets of the company	
minimum determined by the Corporate Law		among the immaterial assets	
Decrease in value	Increase in value	Decrease in value	Increase in value
Reduction of the	Capital increase	Can be a reason for	If the spin-off is
capital, if it does not		modification or	authorized to
threaten the capital		termination of the	commercialize the
(modification of the		license agreement	results of development,
corporate agreement)			the license fee may rise
			or can be redefined
Change in company	If no new patent is	The license fee can	If the spin-off is not
form, fusion, division,	created and the value	be decreased, and	authorized to
cessation without	raises above the spin-	the license	commercialize the
legal successor if it	off's own capital, the	agreement modified	results of the
threatens the capital	part of the above capital		development, the
	is transformed into		coverage and license
	immaterial assets		fee are decreased
			License fee to be paid
			when achieving
			development
			milestones
			("Milestones" type
			royalty)
CAPITAL	CAPITAL	ASSETS REDUCED,	ASSETS INCREASED,
REDUCED	INCREASED	CAPITAL CONSTANT	CAPITAL CONSTANT

Summary:

- 1. The first decision before transferring a technology is whether the IPRs ownership will be transferred into an established company or a spin-off company will be founded.
- 2. When founding a spin-off company, participation of the university should be carefully defined and the relevant legislation accordingly studied.
- 3. It is more suitable if the university transfers the technology to the spin-off company in form of a license and not as a contribution in kind.
- 4. The conditions and methods of the inventors' involvement should be clarified.

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