FROM RESEARCH TO MARKET:
KEY ISSUES OF TECHNOLOGY TRANSFER FROM PUBLIC RESEARCH CENTRES TO BUSINESSES
WHITE PAPER

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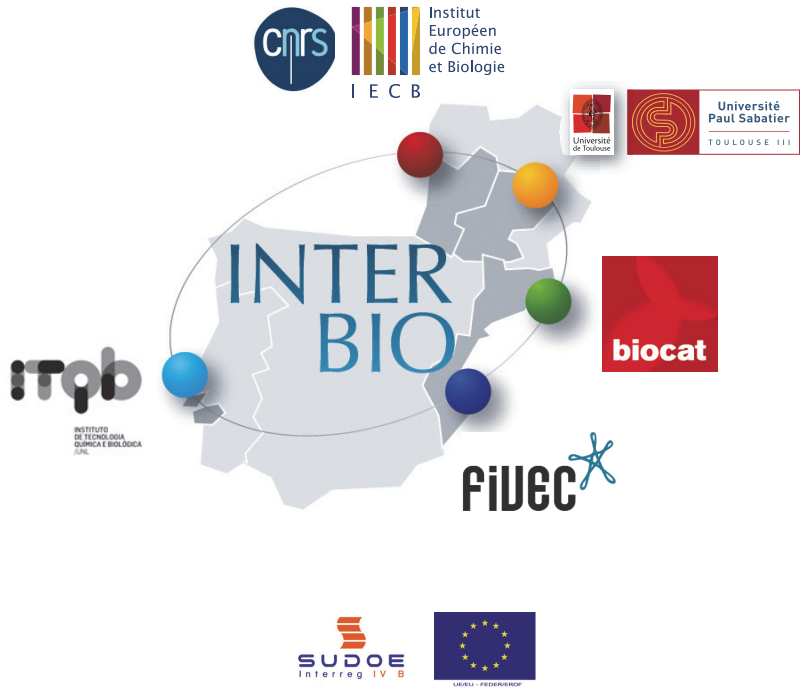

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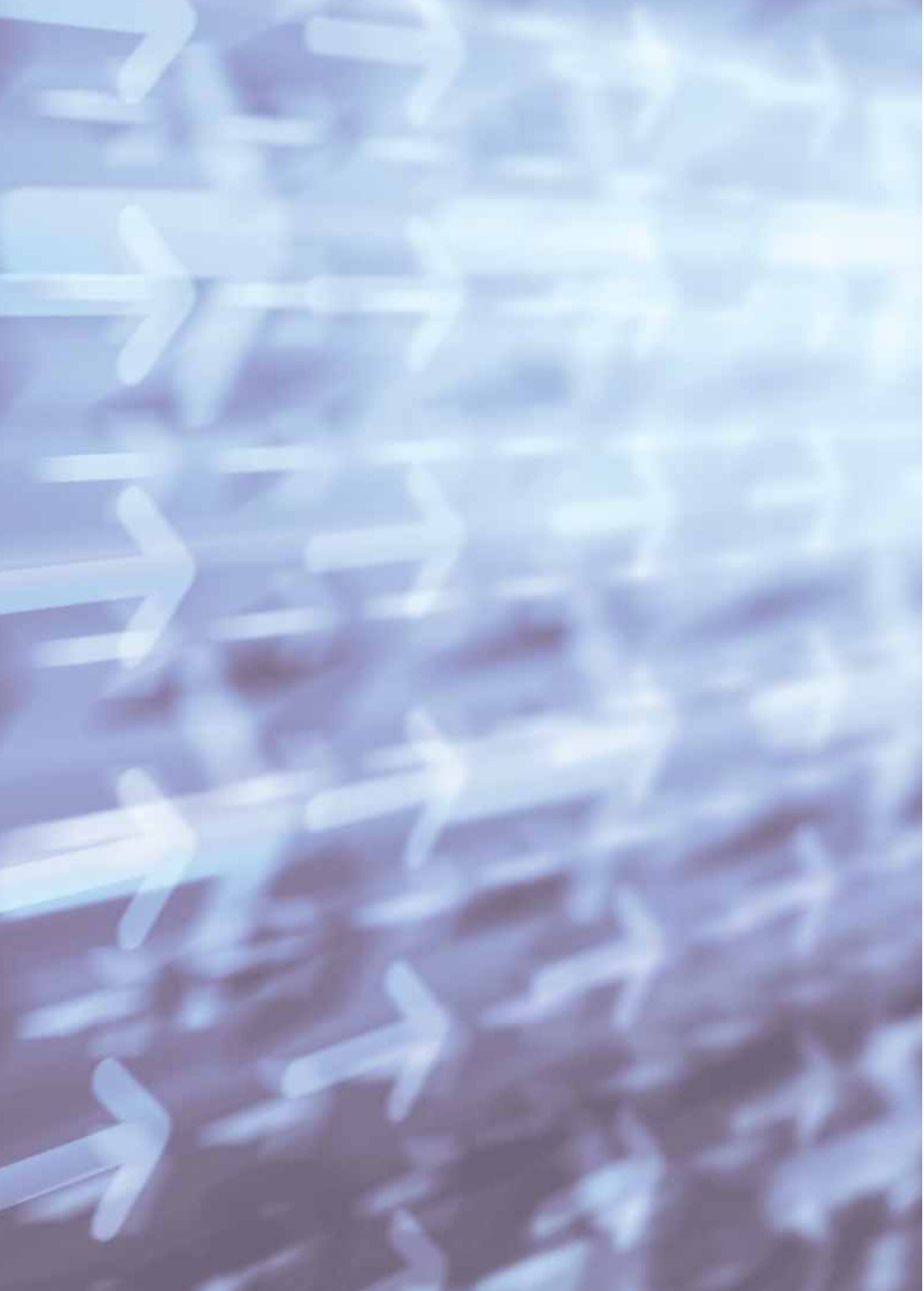


FOREWORD

The SUDOE program (Territorial Cooperation among the Southwest regions of Europe) supports regional development through the co-funding of transnational projects via FEDER funds (European Regional Development Funds). The Interbio project is one of the 28 approved projects within the second call, and responds to the priority of promoting innovation and constituting stable cooperative networks in technological matters in order to favour scientific excellence, competitiveness and innovation through the development of better and cooperation between the different economic, social and scientific players.

The Interbio project seeks to become a **Southwest European benchmark cluster in life sciences** and, among its objectives, we could emphasise its concern for the transferability of results to companies, particularly SME, start-ups and spin-offs in the biotechnologies and health sector.

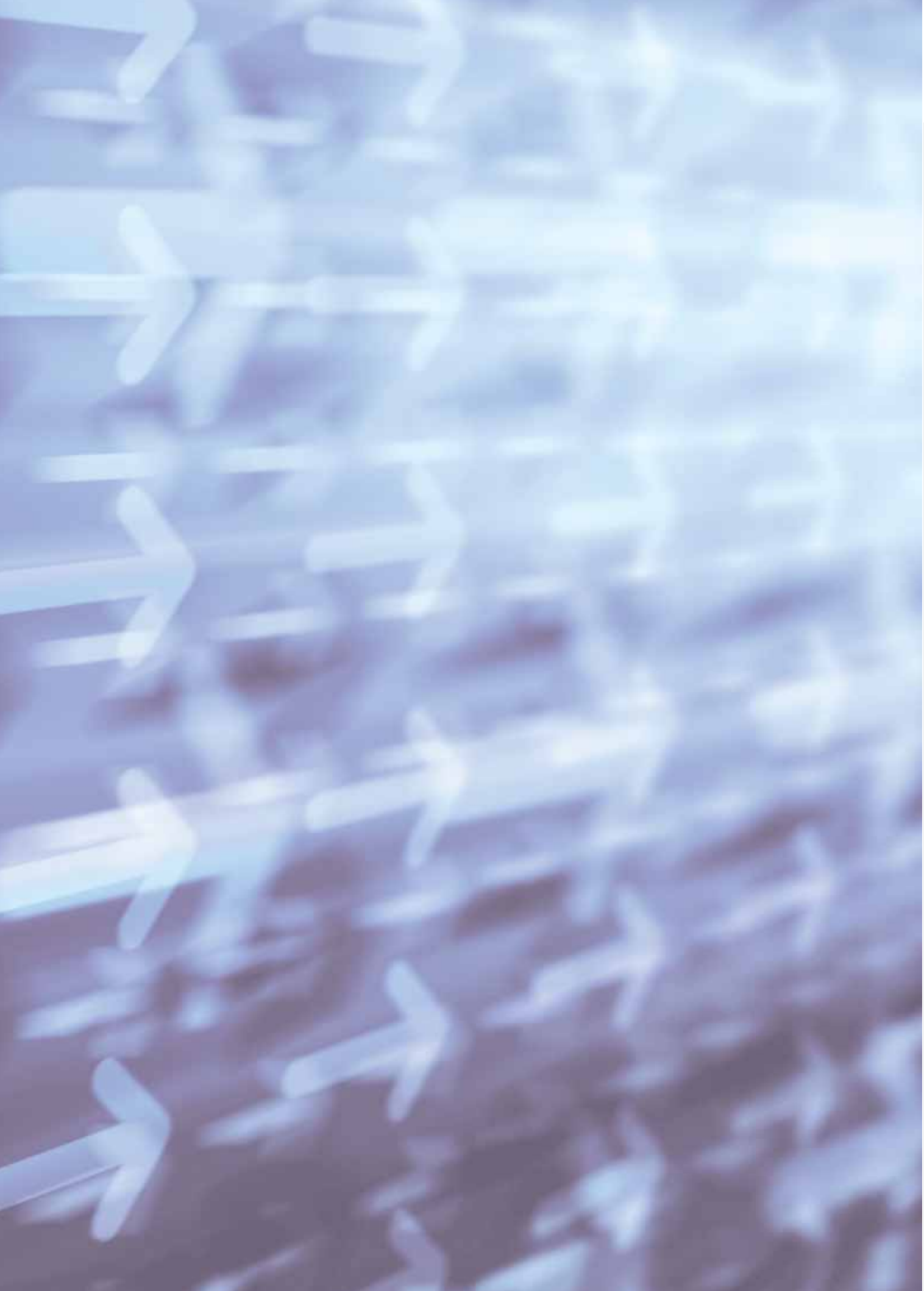
As a strong and patented technology is considered, by both investors and potential industry partners, as a key asset of a SME, therefore the technology transfer process should be conducted with understanding and professionalism.

The Interbio project has tried, through this white book, to provide practical guidelines to a company entering the technology transfer pathway. It provides detailed explanations and key takeaways throughout the process, starting on the identification of the technology, following with the different alternatives to its protection, evaluation and assessment, to finish with the different technology transfer agreements. A “Quick Guide for Technology Transfer to Business” is also provided, which should serve a comprehensive checklist to take into consideration when initiating any technology transfer process.

We are very pleased with the final result, and we are very optimistic about making it a reference book for Technology Transfer actors.

Jean-Pierre Saintouil

Interbio Coordinator of the technology transfer workpackage



1. INTRODUCTION: WHAT IS TECHNOLOGY TRANSFER FROM PUBLIC RESEARCH CENTRES?

As a result of economic globalisation developed in recent years, the European Community has seen the need to strengthen policies in order to increase its global competitiveness and its position on areas such as climate change, depletion of non-renewable resources or demographic change.

So, the European Council, held in 2000 in Lisbon, established as a strategic goal for the next decade a radical transformation of the European economy to become the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion.

The Lisbon Strategy was re-launched in 2005, specifying the key role that a close relationship between public research organisations – including universities – and industry can play in facilitating the circulation and use of ideas in a dynamic knowledge society and in enhancing competitiveness and welfare.

Subsequently, the European Commission identified the need for efforts to be made to improve the conversion of knowledge into socio-economic benefits. Public research organisations need to disseminate and to exploit more effectively publicly-funded research results with a view to translating them into new products and services. The means to realise this goal include academia-industry collaborations – collaborative or contract research conducted or funded jointly with the private sector – licensing, and the creation of spin-offs.

It outlines the importance of creating knowledge transfer offices, with specialised personnel, to improve collaboration and exploitation of research results and their uptake by business, and the need to promote entrepreneurship and cooperation in public research centres.

As an implementation of this goal, the European Commission prepared the communication "Improving Knowledge Transfer between Research Institutions and Industry across Europe: Embracing Open Innovation". In this document, the Commission establishes the following definition of knowledge transfer:

> "Knowledge Transfer involves the processes for capturing, collecting and sharing explicit and tacit knowledge, including skills and competences. It includes both commercial and non-commercial activities such as research collaborations, consultancy, licensing, spin-off creation, researcher mobility, publication, etc. While the emphasis is on scientific and technological knowledge, other forms such as technology-enabled business processes are also concerned."

To promote these activities, the Commission approved in 2008 the Recommendation on the Management of Intellectual Property in Knowledge Transfer Activities and Code of Practice for Universities and Other Public Research Organizations. This document includes a Code of Practice for universities and other public research organisations concerning the management of intellectual property in knowledge transfer activities, with the following principles for a knowledge transfer policy:

"8. In order to promote the use of publicly-funded research results and maximise their socio-economic

impact, consider all types of possible ***exploitation mechanisms*** (such as licensing or spin-off creation) and all possible ***exploitation partners*** (such as spin-offs or existing companies, other public research organisations, investors, or innovation support services or agencies), and select the most appropriate ones.

9. While proactive IP/KT policy may generate additional revenues for the public research organisation, this should not be considered the prime objective.

10. Ensure that the public research organisation has access to or possesses ***professional knowledge transfer*** services including legal, financial, commercial as well as intellectual property protection and enforcement advisors, in addition to staff with technical background.

11. Develop and publicise a ***licensing policy***, in order to harmonise practices within the public research organisation and ensure fairness in all deals. In particular, transfers of ownership of intellectual property owned by the public research organisation and the granting of exclusive licences should be carefully assessed, especially with respect to non-European third parties. Licences for exploitation purposes should involve adequate compensation, financial or otherwise.

12. Develop and publicise a ***policy for the creation of spin-offs***, allowing and encouraging the public research organisation's staff to engage in the creation of spin-offs where appropriate, and clarifying long-term relations between spin-offs and the public research organisation.

13. Establish clear principles regarding the ***sharing of financial returns*** from knowledge transfer revenues among the public research organisation, the department and the inventors.

14. ***Monitor*** intellectual property protection and knowledge transfer activities and related achievements, and publicise these regularly. The research results of the public research organisation, any related expertise and intellectual property rights should be made more ***visible*** to the private sector, in order to promote their exploitation."

All this has led to a significant effort to generate knowledge transfer policies in public research, as well as development of procedures and practices that enable an appropriate balance between promoting innovation and defending the public interest[1].

The process of technology transfer – within an open research environment – can be summarised as follows:

1. Researchers generate results through research activities in a university, research institute or technology centre.

2. They relay the results to the institution con-

[1] FIVEC: "From the academic point of view, interest in knowledge transfer as one of the missions of the university has been seeping between his staff and the number of academics involved in business activities is relevant. All R & D structures that are implemented in our organisations include knowledge transfer, to a greater or lesser extent".

In regard to the business world, companies are beginning to incorporate innovation as one of their values, but have serious difficulties to implement, largely because they have sufficient size and because they move in areas of technical audiences. Have very few staff with technical training that allows them to know how to manage and absorb technology developed at research centres. And the resources devoted to these questions come from government subsidies, so that innovation is more an expense than an investment they have to repay to the operation of your business.

It would highlight several weaknesses:
- Limited funding for enhancement projects and proof of concept that will attract the interest of the companies on research results that require clear doubts for use in a commercial context.
- Lack of a region in the investment industry to know how to develop new knowledge based businesses.

The weak relationship between companies and research centres at times: Often, public research institutions do not understand the real needs of companies and are limited by legal proceedings. In addition, companies are not aware of the skills and know-how of the research centres."

cerned, in particular to the office responsible for technology transfer (protection and disclosure).

3. Through various means, these units communicate to the business community the granting of the patent.

4. Once an external company identifies the technology, the transfer is managed and executed by means of an agreement.

From these elements, this guide explains the specificities derived from the nature as a public entity of Research Centres regarding protection policies and regulatory environment that may influence the technology transfer process involving a public research centre (Chapter 1), it describes the steps and phases to follow by a company that is interested in marketing a technology from a public research centre (Chapter 2) and provides an overview of the most important sources available for identifying technologies with potential (Chapter 3). Finally, the closing chapter "Quick Guide for Technology Transfer to Business" highlights the main questions to be answered and identifies the key issues to be considered through the Technology Transfer process, all of which will have been extensively treated in the previous chapters (Chapter 4).

The approach upon which this Guide is drawn is from the point of view of an external company.

2. WHITE PAPER FOR TECHNOLOGY TRANSFER: PHASES

As previously mentioned, Chapter 2 describes the steps and phases to be followed by a company that is interested in marketing a technology from a public research centre. The Chapter is subdivided in five sections, each concerning a different aspect of the process, requiring specific capacities and expertise to successfully go through it:

- **Regulation of Research in the public centres: Good Practices.** Dealing with public research centres is not comparable to the negotiating process between two private institutions, since they are regulated as public entities. This section explains the specificities derived from this legal situation regarding protection policies and regulatory environment, all of which may influence the technology transfer process and strategies from a private company perspective.
- **Evaluation of the Technology.** The success and quality of the protection strategy of the developed technology is one of the main aspects to determine the value of the transaction. This section provides the indications for evaluating the technology from the point of view of the strength of the intellectual property and explains the concept, procedure and evaluation of the patent, as it is the most relevant means of protection in the biomedicine sector.
- **Assessment and Recovery of Technology.** Technology Transfer requires a phase of assessment (assigning a value to the technology), negotiation with the future owner/partners and recovery (defining and performing the actions to increase the value in a given period of time). This section presents, through an illustrative example, the different valuation methods and explains the negotiation process and the strategies for recovery used in the biomedicine sector.
- **Transfer of public research results to Third Parties: Agreements through licences.** When a result of the investigation is generated and the entity that created it is not interested in its exploitation (either directly or through the creation of a spin-off, which will be considered in the next section), a transfer of the rights to a third party should be considered, either maintaining the ownership (usage and exploitation licence) or relinquishing it (full transfer or sale). This section will cover these issues, as well as insights in respect to the transferring procedure, the negotiation and the Technology Transfer agreement.
- **Creation of a Company as a Mechanism for Technology Transfer.** When the centre is willing to get involved in the development and exploitation of the technology, the most suitable solution is the creation of a Spin-off (term referring to a company created in the environment of a public research entity through the entrepreneurial initiative of one or more participants). This section discusses the main elements to be considered before taking the decision, and once it has been taken, the fundamentals to go through the negotiation of a Shareholders agreement.

Each section is described in depth and provides examples and specifications from the different Interbio regions, these being only illustrative samples from the existing practices and regulations in each region.

A Quick Guide for Technology Transfer is provided at the end of each section, all of which are gathered in the final chapter “Quick Guide for Technology Transfer to Business”, which should be used as a reminder checklist of the main questions to be answered and the key issues to be considered through the Technology Transfer process.

A. REGULATION OF RESEARCH IN PUBLIC CENTRES: GOOD PRACTICES

The technology transfer process in a public research centre has specific characteristics, derived from its nature as a public entity, requiring specific policies. Therefore it's not comparable to the negotiating process that could be followed between two private companies.

For any research institute, an essential element is to ensure the appropriate policies for their protection by applying the existing legal instruments that guarantee ownership and exclusive exploitation. This element will be critical to ensure the subsequent assessment and commercial exploitation of these results.

The importance of these policies to research institutions has been reflected in several documents. In particular, in any public research, it is important to take into consideration the Commission Recommendations of 10 April 2008 on the Management of Intellectual Property in Knowledge Transfer Activities and the Code of Good Practice for Universities and Other Public Research Bodies[2], which has an important impact on this matter.

Thus, one of the recommendations that the Commission proposes to Member States is to encourage the establishment and dissemination of policies and procedures for managing intellectual property.

To this end, the Commission recommends protection measures to be followed by the Member States when determining their policies in this area. Thus, it is again important to highlight the following:

> *"3. Promote the identification, exploitation and, where appropriate, protection of intellectual property, in line with the strategy and mission of the organisation and public research with a view to maximising socioeconomic benefits. To this end, different strategies may be adopted - possibly differentiated in the respective scientific / technical areas - for instance the "public domain" approach or the "open innovation" approach."*

Accordingly, a paramount principle that has been established is to promote the protection of results as a way to support their dissemination and use with greater legal certainty.

State regulations provide for different forms of protection, adapted to the legal nature of the creations developed. In this matter, one needs to pay special attention to the regulation that establishes the ownership of inventions, created within the framework of an employment relationship or services agreement, when determining the fees applicable to both the institution and the researchers for the development of any new technology.

[2] 2008/416/CE, Official Gazette of the EC L 146/19

These regulations also establish the domestic policies that the research centres may develop to regulate the domestic legal framework of research activity and the rights and incentives that will be granted to researchers to encourage them in these activities.

Research Activities: the Attribution of Ownership and Implementation Measures

The public policies of intellectual property specifically establish the scheme of allocation of ownership of new creations or inventions.

To this effect, the general rule is that ownership rests with the person or persons who have created them. However, regulations tend to provide specific regulations for the event that the new creations or inventions have been developed within an employment relationship or a services agreement.

While the general rule is that ownership rests with the person(s) who have created the new product or technology, if it has been developed within an employment relationship or a service agreement, the ownership rights will rest with the employer.

In such cases, provided that the development of this new creation or invention is part of the activities of the employer, the ownership rights rest with the employer[3].

This does not preclude the recognition of certain moral rights – in particular, the recognition of authorship – but the inherent powers linked to the exploitation rights are conferred by law to the employer.

In the context of research bodies, this policy is more pronounced, following the approval of the Bayh-Dole Act in the United States[4], which establishes the ownership of research results generated at universities, small and medium businesses and non-profit entities.

In order to implement and disseminate these policies, research centres often adopt internal rules and include clauses of ownership of any research result in their staff employment contracts.

The internal rules also tend to include procedures to be followed by staff in the case that results obtained from the research activity are eligible for protection, in addition to publication and dissemination policies to be followed by the staff so as not to jeopardise the protection of the results.

Collaborative Research Activities: the Need for Prior Agreements

The purpose of these agreements goes beyond the mere transfer of technology, covering the different stages of any technology development, from research to commercialisation.

This formula allows the centre to obtain funding for its research projects, involving private operators at the early stages of the development of the project.

[3] SPAIN (FIVEC): "The Spanish Patent Act assigns the ownership of industrial property to the employer, i.e, property rights granted on the knowledge generated by employees of an institution (a university or research centre). It is the institution that the company is negotiating with property aspects of performance, when making R & D contract with a company.
The statutes of the institution also regulate the appropriability of the results by the latter and the participation of researcher inventors / authors in the profits of the commercial exploitation of the results owned by the institution.
According to the Community framework for State aid for the European Commission and the Sustainable Economy Act and the Law of Science, Technology and Innovation can only be attributed to the company property when it has funded the cost all investigations have been made to obtain a result or when he pays a market price."
FRANCE (PRES-University of Toulouse): "As a general rule, IP belongs to the inventor's employer. In most cases, it means that the public research organisation owns the patents. In the case of co-development with a company, a patent can be jointly owned or owned by the public research organisation in return for an exclusive licence in the field of the company. If the scientific program is wholly funded by the company, the latter owns the IP."

[4] Patent and Trademark Law Amendments Act, also known as Bayh-Dole Act, enacted by the Congress of the United States of America on 12 December 1980.

On the other hand, private operators involved in the project (that may be specialised companies or financial investors) may be involved at an early stage in the project and define the needs or courses of action to follow, aiming to ensure their participation in any future marketing result. Specialised companies, in addition, may facilitate the development of new innovations that the private sector could not have developed.

This way of cooperation is booming at the present time, due to the need of public centres to obtain new ways of financing their activities and the interest of investors and private companies in the sectors generating innovation. In addition, there is a will by the public authorities to promote these ways of research funding.

The procedures to follow in signing these agreements will depend on the legal framework applicable to each centre. In any case, however, it will require signing a cooperation agreement, which may include the following main aspects:

Main aspects in cooperation agreements are definition of the research project, contributions from each of the parties, monitoring and control of the project, rights over the project results.

- **Definition of the research project**

  An important part of the cooperation agreement is to determine the nature of the project to be developed, which may include defining the results to be achieved and the needs to be covered by this new research.

  The precision in the definition of the results depends largely on the degree of development of the research conducted so far. Therefore, this is determined case by case.

- **Contributions from each of the parties**

  In the case of research centres, their contributions will be the research activity of their researchers (with the right to determine the team or assign the working group) and to grant rights to use existent knowledge and technology.

  On the other hand, private investors will provide the funding to be agreed upon by the parties. This funding may be conditional upon the completion of certain milestones that may be defined in the contract.

  In the case of specialised companies, they may also agree to provide their own personnel in the research activities.

- **Monitoring and control of the project**

  It will be necessary to establish mechanisms to control the evolution of the research project and provide information to private investors. This is usually achieved through monitoring committees with the participation of the parties involved in the project, where decisions will be taken regarding its development.

- **Rights over the project results**

  While the objective of the project is to develop new innovations, an essential element is to establish the ownership of these innovations and, where appropriate, to determine the ownership of the pre-existent technology.

  In the case of activities carried out jointly with other entities in a collaborative partnership, it is necessary to determine in advance the attribution of ownership of the results that are generated through the collaboration. In the contract, it is advisable to include contractual covenants to govern the partnership to avoid future conflicts when the results are generated.

  In general, when dealing with a development request from one institution to another, usually the ownership of rights of exploitation rest with the party who commissioned the matter to the other party. In the case of collaborative projects, this is usually a shared ownership, notwithstanding that either party may retain exclusive rights on their specific development activity.

Finally, if the cooperation of the parties is extended to the commercialisation of the results generated through the creation of a new entity that develops this work, it will be necessary to determine the transfer of rights to that entity.

The creation of this entity, likewise, will require the regulation of the rules that define its organisation and operations, which requires the signature of a shareholders' agreement (which may be negotiated together with the investment contract).

An essential element of cooperation agreements is to establish the ownership of the innovations: Usually the ownership rights of exploitation rest with the party who commissioned the matter. In the case of collaborative projects, this is usually a shared ownership.

Participation of Researchers in the Research Results: the Incentive Policies

As indicated above, the general rules of intellectual property can grant to the employer the ownership of the rights of exploitation of the results generated by its staff as part of their activities.

Nevertheless, this does not exclude the possibility that the worker is paid for his/her discovery, as determined by the Commission in their recommendations:

> *"4. Provide appropriate incentives to ensure that all relevant staff play an active role in the implementation of the IP policy. Such incentives should not only be of a financial nature but should also promote career progression, by considering intellectual property and knowledge transfer aspects in appraisal procedures, in addition to academic criteria."*

Therefore, the regulations also standardise a mechanism for compensation and remuneration to authors and inventors[5], particularly in cases where the discovery exceeds the specific terms of their relationship. In these cases, it is customary to provide a fair price or a share in the benefits of exploitation.

Regulations provide incentive tools for compensating researchers, particularly when discovery exceeds the specific terms of the contractual relationship. In these cases, it is customary to provide a fair price or a share in the benefits of exploitation.

This policy may be applicable also for staff in public research centres[6]. In such cases, moreover, other powers may be provided, such as the allocation of rights to the author or inventor in the event that the relevant public institution is not interested in the technology.

These formulas have a passive incentive. In other words, they do not require the active participation of the researcher in the exploitation of research results.

Whenever the researcher wants to participate directly in the exploitation of technology (e.g., by creating a spin-off), this participation shall be executed in accordance with the legal framework that is applicable (in particular, when the work is done for a public administration), due to the fact that mechanisms of incompatibility and exclusive dedication are usually already in place.

However, particularly in public research, there is a strong political stream to foster the creation of companies and the participation of researchers in these companies. Therefore, public policies are encouraging the creation of new companies from public research centres and encouraging researchers to take the initiative to exploit market research.

[5] FRANCE (AQUITAINE-VALO): "In France, public inventors are directly rewarded when their invention hits the market. The allocation of the licence revenues between the patent owners and the inventors is based on a 50/50 split, once all Intellectual Property costs have been reimbursed. This is a strong incentive for the researcher, but its main drawback is that it is a long term return." SPAIN (BIOCAT): "The Science Act recognises the right of researchers from public research to obtain a share in the gains for the centre for the exploitation of research results, regardless of whether the exploitation is performed directly or by transfer to third parties. The amount of such participation shall be determined by the Public Administration or research centre concerned."

[6] In example, in Spain, by virtue of Section 20 of 13/1986 Patent Rights Act; in France, pursuant to Section R611-11 of the Intellectual Property Code.

Quick Guide for Regulation of Research in Public Centres

REGULATION OF RESEARCH IN THE PUBLIC CENTRES: GOOD PRACTICES

QUESTION 1. ATTRIBUTION OF OWNERSHIP?

Key Issue: Assess the scope of employee activity in the research centre

- Ownership and exploitation rights to the employer (Bayh-Dole Act, USA).
- Eligibility for protection of results: specific procedures.

Key Issue: Ensure prior agreements in collaborative research activities

- Description of the research project.
- Clarification of contributions: activity of researchers, rights to use existent knowledge and technology, funding and milestones.
- Outline of monitoring and control mechanisms of the project.
- Subcontracting or collaborating? Definition of rights over the project results and pre-existing technology, attribution of ownership and commercialisation rights.

QUESTION 2. Participation of researchers?

Key Issue: Consider the compensation and remuneration of researchers

- Recognition of moral rights for the authors (EU Commission).
- Internal regulations of the centre to compensate researchers, especially when discovery exceeds contractual relationship.
- Mechanisms: Passive incentive (fair price, share in the benefits of the centre for exploitation), active participation of researcher (creation of company).

NOTE: Find the complete Quick Guide for Technology Transfer to Business in Chapter 4

B. EVALUATION OF THE TECHNOLOGY

The action of protecting the technology only makes sense when the practice is relevant to a business model of exploiting the technology. For instance, in the free software sector, the protection of technology is not a relevant factor, given that, by definition, it is ceded freely, and the business model is based on the provision of services. In contrast, within the context of biotechnology, the strength of a particular intellectual property is fundamental for the industry's business model, given that it is based on the technology licence and on its subsequent exploitation, which in turn are based on exclusivity rights for an extended period of time.

In the sector concerned, therefore, one of the key aspects of the strategy of any investigation group

is the adequate construction of a defence against and ahead of the competitors, which will facilitate the commercialisation with exclusive rights to the developed products. The success and quality of the protection strategy of the developed technology is one of the main aspects to determine the value of the transaction. In addition, the acquisition of any technology at whatever stage of development requires the buyer to seek proper assessment of the degree of protection of the technology and to take corrective measures if necessary or possible.

In this chapter we will give indications for evaluating the technology in question, from the point of view of the strength of the intellectual property policies.

Evaluation of Intellectual Property

When contacting with a university, research institute, hospital and/or technological institute to acquire a technology, whether or not the technology is protected needs to be evaluated.

The acquisition of any technology requires seeking proper assessment of its degree of protection, since in the biotechnology business model, the strength of intellectual property of a technology is one of the main aspects to determine its value.

The patent, as will be further explained in the next point, is probably the most adequate mechanism to protect a particular technology in the relevant market, although it is not the sole instrument. Other existing ways are utility models (like the patent regarding the right to "prevent", but in this case no new world order, if not just national, and it is given for a limited period of time), copyrights, trademarks, or even industrial secrecy or confidentiality rights of the results of a clinical study in drug development.

The achievement of a patent granted to the inventor of the technology provides the exclusive rights for a limited time, and for a specific geographic area. The patent prevents a third party's use and exploitation of protected technology and thus offers the owner the time needed to bring the technology to market and exploit it more profitably. Despite criticism of this model, the patent serves as incentive, giving the inventor privileges in relation to the exploitation of technology invented and therefore motivates innovation.

Like titles of property, patents can be sold or licenced. The patent is guaranteed by the State, and it is therefore necessary to extend patents in different countries where one wants to protect the technology developed. In Europe, through the European Patent Convention of 1973, there is some coordination in order to extend a patent in different states, giving each of these states their own jurisdiction to resolve any matter relating to patents. There is also a centralised procedure for applying for a patent on an international level, called the Patent Cooperation Treaty (PCT), to protect the patent in every country that has signed the treaty. It is important to keep in mind that this procedure can increase the costs of patent protection, due to the costs associated with patent rights in each country where protection is sought.

Another key issue while acquiring technology is the priority date of a patent. Priority is given to the first in filing the patent. However, filing does not imply publication and therefore there is a period of time where, in fact, the text of the patent is unknown to others. This means that a patent with a preliminary report on patentability – a report that determines the existence of previous publications on the technology – can be positive and then later be declined, to discover that someone had already filed a similar patent but it is still under examination and not yet published. In any analysis of patents, it is necessary to know the state-of-the-art technology goals through the analysis of previous publications and the latest research in order to anticipate potential overlapping patents.

When identifying and assessing a technology that is to be acquired, there are two possible situations:

- **The technology is protected by one or more patents**
- **The technology is not protected by patents**

In the first scenario, the quality of the patent must be analysed, to assure that it genuinely protects the technology to be acquired. It is also important to know whether there are any pre-existing patents that will be needed in order to exploit the technology. Specifically, even when a given technology or invention is

properly protected, sometimes it cannot be exploited commercially, since the use of that technology or invention requires the use by a third party of knowledge or processes protected by a related patent. To determine the possibility of exploiting a particular technology, it is more than advisable to conduct a study called Freedom to Operate (see next section for further details on this report), which can confirm or rule out obstacles when it comes to producing or marketing a product in a particular territory.

To determine the possibility of exploiting a particular technology, the first thing is to evaluate if and how the technology is protected, or if it can be. The Freedom to Operate study and the International Search Reports are more than advisable.

Similarly, on a general basis, identified technology will be protected by a patent that has not yet received a response from the patent office in the country in which exclusivity rights are sought. This situation is common in technology transfer agreements, as patent approval can lapse for a period of more than five (5) years. Hence, it is necessary to know the chances of success of the patent process by requesting preliminary reports on patentability, preliminary reports called International Search Reports (ISR), as well as the opinion of the patent examiner, who will provide an opinion, before the final approval of the patent is given, on the novelty of the claims included in a patent, accepting or rejecting them, as well as identifying those prior public documents (patents and publications) that conflict with the body of the patent or any of its claims.

Finally, sometimes the technology to be acquired is not patented. In these cases, the initial objective is to evaluate the possibility that the technology goal can be patented. To do so, a preliminary study of the patent should be conducted. A study by *Freedom to Operate* is also advisable to analyse markets in which there is leeway to evaluate the size of target markets.

The Patent: concept and procedure

The patent is a right granted by a state monopoly on a technology, a right that is provided in exchange for the inventor's sharing of the technology, in other words, for having made the technology public by publishing the patent.

As previously mentioned, the patent is not the only way of protecting a particular technology, but in the relevant market, it is likely the most relevant, given that (I) it is necessary because development costs for exploiting the product internationally are usually high, and (II) it is necessary to ensure a period of exclusivity for a lengthy period of time, to have time to administer the necessary investments in the field of development of pharmaceutical products or medical devices. In any case, it is important to know that there are other ways, such as utility models (like the patent regarding the right to "prevent", but in this case no new world order, if not just national, and it is given for a limited period of time), copyrights, trademarks, or even industrial secrecy or confidentiality rights of the results of a clinical study in drug development.

A patent essentially consists in the description of the innovation that is to be protected, including claims about specific aspects of innovation (processes, steps to reach the invention, new concrete), which will ultimately be what is going to be protected –which may not be accepted in its entirety– and the supporting information (embodiments) that justify the ownership and suitability of the claims, all of which will be stronger the more data and evidence are submitted in its favour. The patent, as discussed, is essentially a commercial instrument. The exclusivity granted by the state guarantees the right of monopoly over the protected technology.

In order to be patented, a technology must demonstrate novelty, inventiveness and that it can be applied industrially.

- To demonstrate the novelty on a worldwide scale, the technology must not be qualified as current state-of-the-art knowledge (pre-existing knowledge). The prior art consists of everything, dated prior to the submission of the patent, has been accessible to the general public. In summary, the prior publication of any information regarding the body of the patent, including any publication or even a conference, means that this is not new and therefore not patentable. Note that careful

attention needs to be paid to this particular issue when dealing with public research environments where protecting specific technologies may very well be in jeopardy due to previous disclosures in scientific publications.

- The inventiveness is usually more of a subjective matter, because it depends solely on the perception of the examiner initially and then, once the patent is published, third parties who may protest its content. A technology to be patented must offer innovations that are not obvious to an expert in the field, i.e., which cannot be inferred from the combination of previously published information.

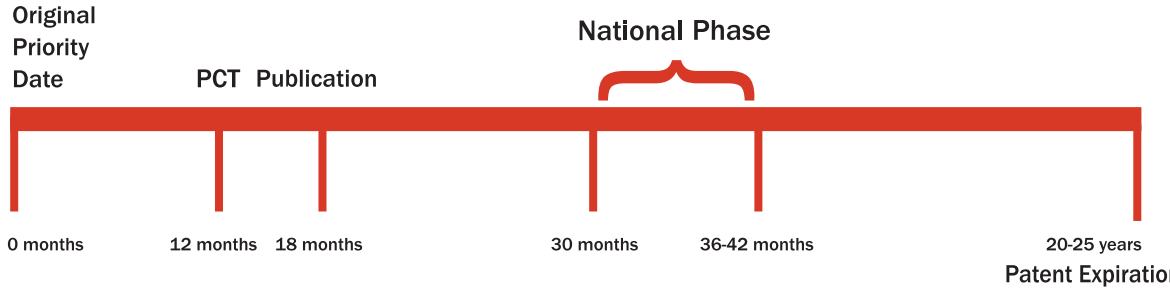
- The industrial application of the technology implies that it must be produced or used in an economic activity, i.e., the product should be applied and not be purely theoretical.

Finally, theoretically, since the compensation for the monopoly granted by the law is the publication, the description has to be clear in the eyes of an expert, so that it can be reproduced at any given moment.

Key elements for patenting are demonstrating novelty, inventiveness and industrial application. To improve the scope of protection and the granting chances, it is normal practice to enrich the claims and embodiments of a patent until publication.

having filed the patent. The patent will not be published (being then entered in a database which is accessible to all) until 18 months have elapsed since its application. Then the process truly begins. One by one, each office may present its objections to the content during the phases of registration in each country where the applicant seeks to extend the patent. As mentioned earlier, it is very common to evaluate technologies that are in this process/phase of completion (application has been submitted but not yet published nor approved). In this part of the process, it is interesting to know that until its publication, in certain cases, the patent can be enriched with new claims and embodiments that will improve the scope of protection sought and succeed in increasing the chances of being granted. A patent may be rejected if the claims and supporting data

Figure 1: PCT Patenting processes timings



The patent process is a long and complex process. The first opinion of the examiner with regard to novelty, inventiveness and description of the patent application takes a minimum of 12 months after are incorrect and/or insufficient, so it is normal practice, after filing the application for the first time, to add additional information or new findings from experiments that improve the quality of the invention.

The Patent Office shall appoint an examiner to be in charge of analysing the patent and who will evaluate the application form of the patent. Initially, s/he will focus on ensuring that the application form has been filled out correctly. This assessment is normally done immediately after the filing of the patent. Later, the reviewer, who has bilateral contact with the applicant, analyses the state of the art on which the patent stands, studying existing patents to date and scientific publications that exist in the area. The result of this analysis is presented to the company in response to their patent application. This evaluation is critical because it identifies those patents and/or published information that conflict with the claims that the patent defends and therefore can pose doubts on its novelty (issues that have been published previously, which prevent considering it as such) and its inventiveness (i.e., previous publications do not coincide completely with the claim, but in the opinion of the examiner, the combination of different information would allow developing the technology claimed in our patent).

In fact, analysis by the examiner identifies those claims affected by previously published information, arranged by type of collision. The identification of collisions with previous documents are usually identified in this report with different letters, with X and Y being the most important (respectively identifying direct collision with a previous document, and collision with different documents if they are combined). Obviously, a report on patentability with several Xs and Ys is not usually good news. The report of the examiner opens the possibility to answer the negative opinions about the claims that conflict with previous information and the state of the art. This allegation can be made by providing information and explaining reasons for the novelty and inventive level.

In today's world and in the biotechnology sector in particular, it is difficult for developed technology not to overlap with any previous technology. Large corporations spend millions of dollars on their intellectual property strategies, which result in real legal battles designed to clarify who is the rightful owner of the related patent families that are dependent on each other. The goal is to compete, as in any market, and reach agreements that allow the exploitation of technology and determine the value of compensation necessary to the third party that holds or claims to hold the intellectual property rights.

In the process of evaluating a patent application, the examiner will assess the state of the art on which the patent stands, the existing patents and scientific publications in the area and the potential conflicts or collisions with the defended claims.

For a research group with more limited resources, it is difficult to establish a clear strategy in relation to the product, and hence one should bear in mind that:

- The strategy of protection technology should allow discrimination on the possibility of progress or not in a line of inquiry
- The strategy of protection technology should allow discrimination between different possible lines of research (priority products that are easily defended)
- The protection strategy can pass to reach agreements with third parties for the right to end the exploitation of the patent

A patent that has already been issued may be subject to further analysis related to objections raised by third parties (who have had access to the text of the patent, which until then had been unpublished and therefore inaccessible) to the examiner, including again the assessment of inventive step, novelty, possibility of being industrialised and the quality of the description. On the other hand, keep in mind that a patent may be revoked because of a regulatory or legislative change in the country in which the patent has been granted.

Patenting Strategies

There are different strategies for applying for a patent –which is in itself a very complex process. The European patent initiates procedures for requesting protection in about 20 countries at a time, which simplifies the process and also has the advantage that it involves a nonbinding preliminary report called European Search Report (EESR). This report contains the opinion of the first examiner, obtained 6 months after the request, and is useful for anticipating the problems that the patent application will face. Recall that the texts of both the patent and the report remain private.

However, one advantage of the national route is the reduced cost of the fees associated with the patent. These fees are waived for public research institutions. Note that when applying for a patent, only the fees are paid, discounting the cost related to independent experts who regularly participate in the process, and paying for the national rights of use and exploitation at the time that they apply for these rights to be extended in different countries. Since this route is cheaper, and a priority date for an international patent is given – which is important in the beginning – this approach is usually chosen by many public research institutions and universities.

If the European route is selected, the European Patent Office (EPO) will publish the report with the answer 18 months from the priority date, which thereafter opens a six-month period for paying the corresponding fees to the countries covered by the European patent and asking for the Substantive Consideration of the application, in which the applicant may respond to the comments of the examiner.

A common option worth considering at this point is abandoning the European and / or national patent (already started) in favour of the request for the Patent Cooperation Treaty (PCT), keeping the priority date of the national patent and/or the European. This implies that the national phase is delayed by 12 months and does not occur until month 30 and therefore permits making significant deferments in the costs associated with the patent process. The PCT provides a single patent office (national) as a reference, which acts as a representative of the more than 100 countries that have signed the treaty. In any case, it is important to note that the PCT is not a patent-granting procedure nor does it replace the national concession. It is in fact a unified system for processing the initial phase of the request.

There are different strategies for applying for a patent: National, European (20 countries) or through the Patent Cooperation Treaty (PCT, unified system for > 100 hundred countries).
The chosen strategy will depend on timing, geographic and economic priorities.

So with this option, 12 months after filing the patent with the European Patent Office (or the national office), the PCT is presented claiming the priority of the national or European patent. At this time there is also the opportunity to change the text of the new PCT application, using the comments that the examiner has made if the examiner has followed the European route. All additional materials included in the PCT have a PCT priority date, while the other (original patent) will have the priority date of the patent above. Six months after filing the patent, the report of the European Office of the PCT is received, abandoning thereafter the European application. The objective of this manoeuvre is to delay payment of the fees associated with extending patents to different target countries, as, with the PCT, this action is deferred a few months. The down side is that the process slowly reduces the time given to exploit the technology in exclusivity.

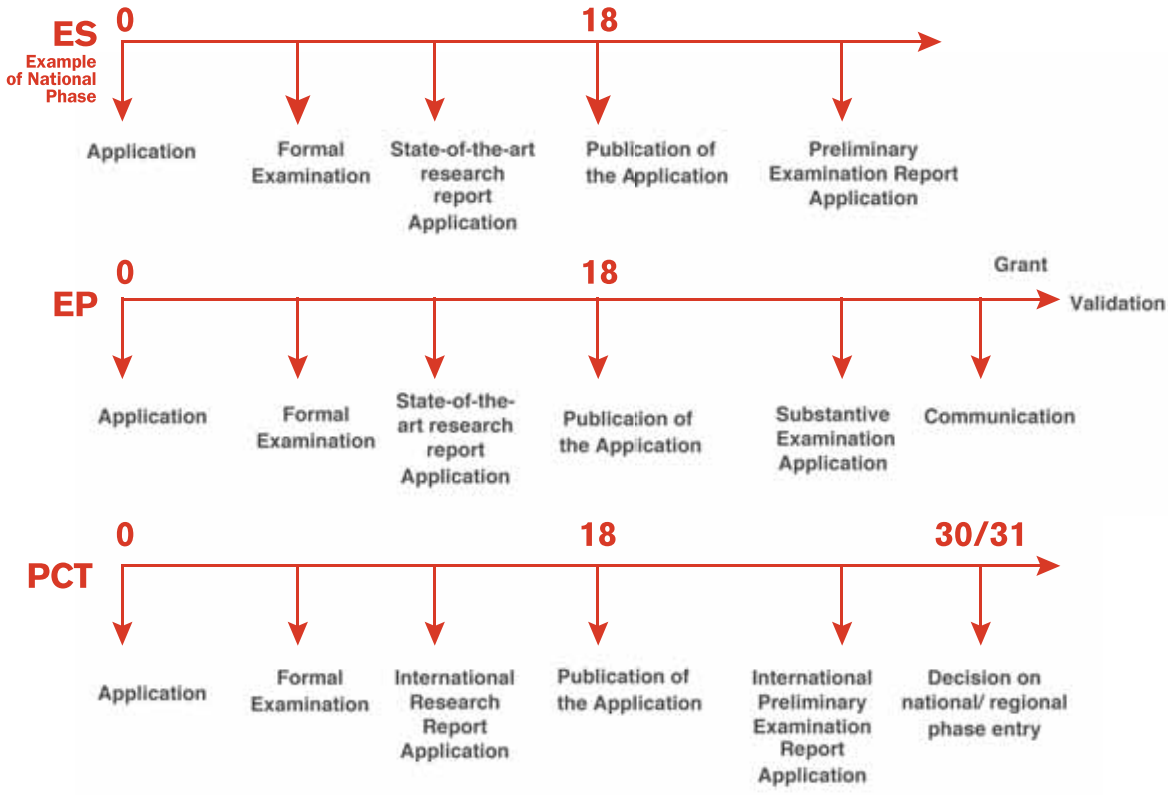
The PCT, which can also be requested directly from the start, provides the benefit of a preliminary report on the state of the art of the technology, which anticipates data on the patentability of the invention. The international phase begins with the realisation of the International Search Report (ISR) previously mentioned, which aims to discover the state of the art, a process that is carried out based on the claims of the patent. On the basis of the ISR, amendments to the claims can be made. The International Bureau of the World Intellectual Property Organisation (WIPO) publishes the international application together with the ISR within 18 months of filing the PCT application. Prior to this publication, the International Bureau shall convey the results of the ISR in each designated national office.

On the international stage and upon the request of the applicant, it is possible that the PCT is the subject of a preliminary examination conducted by the International Preliminary Examination Authorities (IPEA). If the applicants decide to combine national patent/PCT in Europe, this report must be requested within a maximum period of 22 months from the priority date of the first patent application. This review aims to present a preliminary opinion on compliance with the requirements of patentability. Although this report is not binding to any member state of the treaty, the results are taken into consideration by the respective national offices.

Finally, as for the national patents, it is necessary to enter the respective national stages, usually 18 months after the PCT application. This entry involves the payment of a series of fees (initial and maintenance), which represent the true costs of the patent. After 3 to 4 years from the time of the entry into the national phase, the research reports of the examiners of each country where the PCT has been applied will arrive.

at the time of reaching the national stage. Otherwise, once the correct state of the art is known, and it is clear that extending the patent to the U.S. and Europe is what is most desirable, the PCT may be avoided, and steps to initiate patent protection can go directly through the European Patent and U.S. Patent offices. The following table shows a comparison of different routes for filing for patent protection:

Figure 2: Timings of different patenting processes



The procedure described above is not unique, though it usually follows the aim of delaying the national entry phase and thereby avoids the most costly stage of the process. The applicant can choose different ways, such as a direct request to PCT, because this is not a way of registering patents (as explained above), but only a way that unifies the registration process in the previous phase, that ends

Evaluation of the Patent

The company interested in acquiring a technology can be found at some of the points (mentioned above) in the process of protecting the technology, provided the research group or university that has promoted the technology has determined the need to protect it.

In order to define the necessary actions in acquiring and evaluating the technology, different situations that can be encountered in relation to the process of protecting intellectual property may be summarised as the following:

- The technology has not been patented.
- The technology has been patented and it is at a particular point in the process of protection or it is in a phase of national protection.

a. Unprotected technology

The constant relationship with a research group or centre for research may lead to show interest in a technology or process and to consider strategic purchase, even if it has not yet been the subject of protection. The decision and determination of the purchase price, as in the case of the existence of a patent, require prior analysis, both from an economic point of view and a technological point of view. In this analysis, however, a study of the possibilities of patenting the identified technology must be added. In short, technology that has potential should fulfil these two considerations:

- It has promise for increasing its own economic value.
- It can be protected, ensuring a proper exploitation.

The economic evaluation of the technology will be dealt with in the following section, "The valuation of technology". The logic of any economic analysis process can be included within the definition of valuation, taking into account the difference between the acquisition price and the eventual price of sale: technology assessment (including determination of the superiority of technology and identifying the existence of alternative technologies), market research (including the demand for technology and the subsequent identification of potential licensees), cost of technology development and the protection and subsequent exploitation of this technology.

From the standpoint of strict protection of intellectual property, the acquisition of technology must be conditioned to provide, firstly, the need to protect it, and secondly, the ability to protect it. Regarding the first point, as mentioned, a patent is not always necessary, and there are other mechanisms in order to enjoy exclusivity and / or protect technology against competitors. However, in the sector in question, the patent is usually essential, since this is the basis for negotiating the sale or licensing of technology.

The technology under interest may be patented, in the process or not patented at all. In the last case, the most important element is to evaluate the advisability and possibility of patenting (novelty, non-disclosure, research process under standards)

Given that the first 30 months from the publication of a patent have a relatively low cost, research groups or public research bodies increasingly initiate directly the drafting of the patent for the technologies considered minimally interesting, or not envisaging a possible transaction. This emphasis on drafting patents has advantages and disadvantages. Among the first one that clearly stands out is the growing commitment to the social return on public research, which has no other way to return to the market - and therefore to society - than the patent process. This commitment results in a greater ability to acquire public technology (identification of technologies and facilities in the transaction). Among the disadvantages, the main one is the low level of quality of patents coming from a public source, despite the improvements made by the technology transfer offices in charge of these affairs. The patents in this area are completed with insufficient data and no previous studies of patent rights (these are in fact expensive) and are often exclusively focused on the development of the scientific curriculum of the researcher. With the lack of coordination between the objectives of patenting on the one hand and publishing on the other, innovations are part of the intrinsic nature of these centres.

Whether we collaborate regularly with public research institutions and thus have access to data and/or results on a regular basis or because we have been aware of this technology, the expected results of the evaluation to patent a technology of interest could be either of the following two scenarios:

- **Not worth protecting the technology and/or the technology cannot be protected.** In this case, if the decision is to continue exploiting the technology, it would make more sense to opt for collaborative agreements with a research group that allow for the exploitation of the technology and access to know-how, given that a real transfer of technology cannot be produced as it does not exist in the form of an asset.

- **There is an interest in protecting the technology and likewise it is possible to do so.** Here the process of technology protection begins, **ownership of which will remain with the public centre,** being transferred in a later stage. That is, the public centre will start (with the collaboration of the buyer) the patent process, for a later transfer of this asset. It is important to collaborate in and even to coordinate this process, because the successful execution of the patent process may be controlled by active involvement.

The question at this point is: is it possible to protect the technology? The keys for carrying out this process appropriately are:

- Analysing novelty of the technology to protect, through an initial literature search. To perform this task, a public web search for patents and publications, such as those managed by the European Patent Office and the analogous (www.espacenet.com and www.uspto.gov) can be used. In this regard, although part of the process can be carried out independently, it is necessary to have an expert in protection of intellectual property, such as a patent agent. The most common request for information about the patent and the possibility of further exploitation of the technology can be answered in the form of two additional reports, as follows:

  - **Report of patentability.** This is a private report conducted by an independent expert, which emulates or should emulate reports on the state of the art of the technology produced by the Patent Office. Using the data presented, it evaluates the possibility of carrying out successfully a process of application and registration of a patent, given the state of the art of the science and those patents that may enter in conflict with it. Since conflict with other patents is very likely, the report may recommend what the most appropriate strategy for protecting the technology is and which claims are necessary to emphasise, (e.g., if a more an extensive and/or more generic patent or a patent more focused on a particular point is needed). Without being able to answer conclusively, this report let's you to discard particular technologies or choose between different possible uses for a technology, based upon the real possibilities of their protection. As mentioned above, note that the consulted expert, by not having access to patents that have not yet been published, may omit relevant information that could later invalidate the study and therefore the patentability of the invention.

  - ***Freedom to Operate* Report**: Although technology is patentable, its commercial exploitation (ultimate goal of this process) may not be possible. This is because the process of manufacturing the product, or any of the steps taken in its development, may conflict with any patent owned by a third party. It should be noted that the focus of this report is qualitative and requires intimate knowledge not only of the technology itself, but also of the industry value chain and the associated production processes. For example, it is probable that an innovative biomarker is patentable as a diagnostic tool, but in order to exploit this tool, it is necessary to use a device. Following this example, it could be that the use of this device infringes on the rights of third parties, giving rise to what is called a "dependent patent". The exploitation of a dependent patent requires the authorisation of the owner of the patent, and this is therefore a constraint to consider.

    Freedom to Operate studies go beyond what can be covered here in this White Book, though another case worth mentioning is that of a clinical trial related to drug development: after having successfully completed a clinical trial, the study of a particular molecule which supports the invention patent is suspended. In this case,

there is a positive Freedom to Operate report. The patent may have been invalid for lack of inventive height but was valid due to its inventive novelty, which is what gives rise to the exclusive property of the data. So the clinical trial then has a right to exclusive use for 10 years. Therefore, despite not having the patent ownership of the data results of the trial, the patent owner has an advantage over competitors who have to wait 10 years to start the marketing of generics or face the time and costs of repeated relevant clinical trials.

- Analysing other key aspects for the process to be successful, such as that the data and results used in the investigation were not in any way made available to the public. Any article or conference citing inventions may invalidate a future patent, cancelling out the condition of novelty. Whether there are confidentiality agreements with third parties who have collaborated in the research must also be considered.

- Checking that the research processes undertaken have been documented accurately and using standards approved by the respective patent offices. For example, in the case of extending a patent in the United States, records of the laboratory results must be maintained.

- Studying the right moment to apply for the patent. The strength of a patent depends on the amount of information and data that is included in the application, but the very act of collecting information could delay its grant and hence put the applicant in a weak position in the race with competitors, risking loss of novelty. On the other hand, filing a patent prematurely may result in a weak patent, which subsequently cannot be completed and thus makes it less effective. It also could result in consuming more time of the exclusivity period that guarantees the patent in the development of the product instead of having that protection while it is in the market, allowing competitors to know the content of our patent.

b. Technology in the process of being protected

It is common for the office of technology transfer to begin – but not complete – procedures for patenting the technology to be purchased. In this case, as in the previous, analysis of the technology includes the need to economically evaluate the patent, dealt with in following chapters. In addition but independently speaking, whether the strategy of protecting intellectual property has been well designed and is being or has been well executed will also be analysed.

If the technology is in the process of being protected, the buyer should analyse whether the intellectual property strategy is well defined and executed, and aligned with priorities in terms of expansion and timings.

For this phase of the process, the applicant should seek the help of an expert in intellectual property to support the buyer in the due diligence process in order to anticipate problems in the evolution of the patent. Initially, the buyer should pay special attention to the following factors:

- That the patent includes the names of the authors of the successful development of the technology in question. This point is especially relevant with respect to patents in the USA, as any omission may mean that the patent could be invalidated.

- That the patent covers key aspects in relation to the technology that should be acquired, i.e., that the patent covers what we sell. The most usual case is that the technology or product to be developed is not fully protected, because the patent is built around some of the processes or products in key technology development (and this is the only thing that can really be patentable). In any case, it must be analysed whether the patent protects technology acquired in a sufficient and guaranteed form to protect against offensive and defensive strategies with respect to competitors.

- As in the previous case, whether the information was treated confidentially to ensure there is no impediment to future approval of the patent must also be analysed.

- If the patent has been granted in some countries, make sure that the fees have been paid correctly.

The path chosen by the public research institution in terms of the patent will determine the action to analyse at what stage the protection process is. The interest of the patent owner in postponing the costs of aggressive expansion of a patent may not match the buyer's interest in accelerating this process. Therefore corrective actions are necessary not only aimed at improving the body of the patent.

It is important in this regard to have access to preliminary reports on patentability, those prepared the European way as well as those prepared by the PCT. It is important to recall that both ways request a series of previous reports from the examiner to ensure information about the state of the art, and in the case of the PCT, these reports have often descended on the various national patent offices. These reports facilitate the assessment of whether the approach of the patent is correct and what risks will be assumed once the technology is licenced or acquired in relation to the appropriate evolution of the selection process. Technology transfer contracts usually separate the licensor or seller of any representation or guarantee regarding the future evolution of the patent. Therefore, measuring the risk of success or failure of the examiner's hand is also vital, especially when advance payments or down payments for the purchase/licence of the technology are involved.

An unfavourable firstly opinion by the examiner should not necessarily mean discarding the target technology. Firstly because there may be alternative protection mechanics and secondly because this opinion can be formulated in a previous stage or rebated, allowing a defence by presenting additional documents to rebate the examiner's opinion. The process of examination of a patent is a long process, which provides for interactions between the examiner and the applicant, who can enhance the application with additional data to justify and defend specific claims.

If there are no reports yet available regarding the state of the art of the technology expressed in a preliminary form in the European patent or PCT, or on a permanent form, in parallel with its grant, there will be the need to emulate them in collaboration with an expert. The aim is also to discover any possible existing patent disputes relating to the intellectual property. In any event, special attention must be paid to the content of the claims, given that there are different categories of product, process and use.

It is also crucial to measure the risk of success based on reports of patentability provided by patenting authorities, although an unfavourable first opinion by the examiner should not necessarily mean discarding the targeted technology.

If this report has been made, it is highly recommended to order, as in the previous case, a report of Freedom to Operate, to determine whether the patent has entered the national phase or not. This report will enable the applicant to anticipate the existence of any limitation on the production phase and/or services and, at the same time, identify the offices of other patents or other patents.

Quick guide for evaluation of the technology

EVALUATION OF THE TECHNOLOGY

QUESTION 3. IS THE TECHNOLOGY PROTECTABLE?

Key Issue: Evaluate the protection strategy

Protection strategy: should respond to the relevancy of business model to exploit the technology.

- Protection in biotechnology usually done through patents (monopoly right granted by the state over a technology for a limited time and a specific geographic area).
- Other protecting tools: utility model, copyright, trademarks, industrial secrecy, confidentiality rights,...
- When resources are limited, protection decisions should be aligned with research strategy.
- Initial 30 months have low cost, thus public research bodies increasingly initiate the drafting of the patent.

  Advantages: it demonstrates growing commitment to the social return on public research and greater ability to acquire public technology

  Disadvantage: despite technology transfer offices efforts, still low quality of patents, based on insufficient data and lack of previous studies of patent right

Key elements assessed in a patent:

- Date of priority (first in filing).
- Novelty: must not be qualified as a pre-existing knowledge accessible to the general public.
- Inventiveness: offer innovations not obvious to an expert in the field.
- Industrial application (not merely theoretical).
- Reproducible at any given moment.

QUESTION 4. HAS THE TECHNOLOGY BEEN PATENTED?

Key Issue: Technology patented – Verify:

The patent duly includes the technological development author's name. This point is especially relevant with respect to patents in the U.S.

The patent provides sufficient protection for the acquired technology and ensures solid holding.

The information has been treated confidentially.

If the patent has been granted in any country, confirm that the fees have been duly paid.

Key Issue: Patent in process – verify:

Priority Date (given with the filing of any king of patent: national, European or PCT).

Protection strategy matches buyer's interest - corrective actions for patenting process may be done by the buyer depending on the stage of the process.

- The strategy of abandoning National / European patent in favour of PCT permits the delay of payment of patents extensions but slowly reduce exclusive exploitation time).
- A patent can be enriched until publication with new claims and embodiments to improve the scope of protection and increase the chances to be granted.

Ensure availability of **preliminary reports on patentability** to anticipate problems in the evolution of the patent (or emulate them in collaboration with an expert) and a report on ***Freedom to Operate*** (identify potential constraints for commercial exploitation).

EVALUATION OF THE TECHNOLOGY

QUESTION 4. HAS THE TECHNOLOGY BEEN PATENTED? *(CONT.)*

Key Issue: NOT PATENTED– Analyse and protect:

Evaluate the convenience of patenting the technology (necessary to have an expert in protection of intellectual property involved):

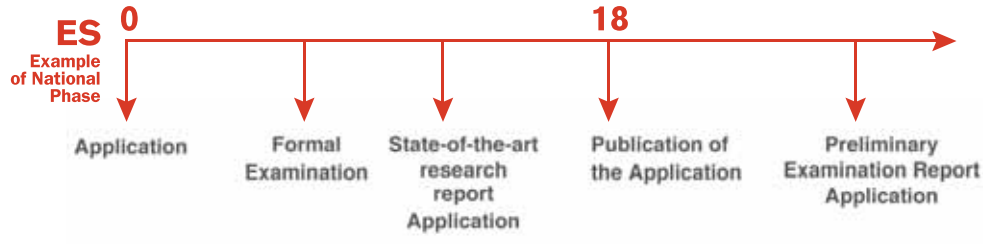
- Not worth protecting or the technology cannot be protected: opt for collaborative agreements with the research group.
- Interesting and likewise to protect the technology: ownership will remain with public centre, which starts the patenting process with the active involvement of the buyer.
  - Technology to be acquired can be improved and recovered economically.
  - Technology to be acquired can be protected, ensuring proper exploitation.

If the technology shall be protected

- Analyse the patent: Patent literature search through websites www.espacenet.com / www.uspto.gov and scientific publications, especially those published by the Centre.
- Confirm that data and results used in investigation were not in any way made available to the public (Any publication before the patent can mean an end to the novelty required for a patent).
- Verify that the processes of research carried out in relation to technology have been documented accurately, using standards approved by the respective patent offices.
- Request for Patentability Report (private report by independent expert) and Plan for the Strategy of Protection of technology through experts. Important: These experts will not have access to patents that have not yet been published.
- Report of Freedom to Operate (identify potential constraints for commercial exploitation).
- Analyse the right time to introduce the patent (the strength of a patent depends on the data and information included in the application).

Key Issue: Choose the most adequate patenting process

National Patent.



Advantages: reduced cost of fees in the initial stages (waived for public research institutions); often used by research centres. Provides Priority Date.

Disadvantages: it is necessary to replicate the process country by country.

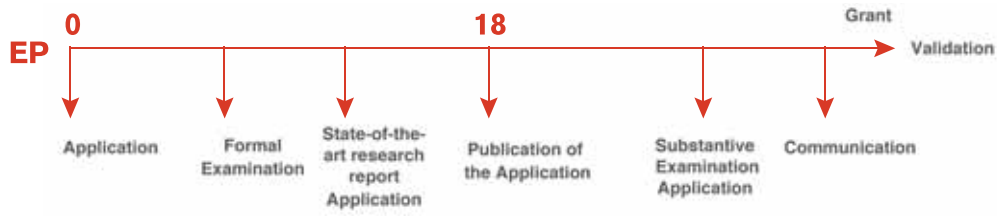
Documents to be analysed:

- Text of the patent
- Freedom to Operate (experts)
- Previous reports on patentability (experts)
- Reports of the Examiner (national office)

EVALUATION OF THE TECHNOLOGY

QUESTION 4. HAS THE TECHNOLOGY BEEN PATENTED? *(CONT.)*

European Patent (about 20 countries)



Advantages: single request for Unified European offices. Provides Priority Date.

Disadvantages: payment of fees.

Documents to be analysed:

- Text of the patent
- Freedom to Operate (experts)
- Previous reports on patentability (experts)
- European Search Report (EESR): private non-binding preliminary report.
- Availability of European Search Report published by the European Patent Office (private report, at 6 months from the application submission)

Centralised procedure: PCT (Patent Cooperation Treaty, unified system for processing initial phases of request in about 100 countries)

Advantages: unified international process

Disadvantages: payment of fees

Documents to be analysed:

- Text of the patent
- Freedom to Operate (experts)
- Previous reports on patentability (experts)
- Possibility to request International Preliminary Examination (IPE)
- Availability of International Search Report (ISR) published by the International Bureau (WIPO) (public report 18 months after submitting the PCT application)

National extensions

- Evaluation of each country; payment of fees by country; part of the process is more expensive.
- Documents to be analysed: Objection by third parties

NOTE: Find the complete Quick Guide for Technology Transfer to Business in Chapter 4

C. ASSESSMENT AND RECOVERY OF TECHNOLOGY

Technology transfer requires previously a phase of assessment and recovery, at least in its classical definition, both the accounting and its development in the context of the literature surrounding the research. This phase allows for greater legal certainty to the research centre at the time of transferring rights of the results to third parties.

The terms *assessment* and *recovery* of technology must not be confused. The first term involves assigning a value to technology. Technology is an intangible asset and, therefore, its assessment involves certain difficulties which will be addressed later in greater detail. When it comes to acquiring technologies in early stages of development and the technology is far from market – as is usually the case when the transfer occurs between academia and industry – these difficulties increase. Meanwhile, recovery involves action value, which could be defined as performing the tasks necessary to increase the value of a technology in a given period of time. Although recovery is applicable to any technology at any stage of life by definition, it is in the early stages when the technology is still a green strategy for systematic recovery that it can have a multiplier effect of more relevant value.

The valuation of a technology requires first an *assessment* (assignment of a value) and then a *recovery* (implementation of the actions aimed at improving its value).

No matter how simple actions aimed to develop the technology have been, the fact that the developer was able to transfer or sell it means that a third party has valued the technology and is willing to pay a price for it. Therefore, it can be said that the developer has managed to sell the technology when it has been recovered, has carried out actions directly or indirectly to give the technology an economic value, and then has sold it. In the previous chapter, we have seen how protecting intellectual property (in the initial phase of a technology) is the most evident way to value. Technology significantly increases its value when patented, so that its value can be zero if you have resigned, voluntarily or involuntarily, to its protection.

Similarly, technology with an immaculate *Freedom to Operate* report is worth more than technology dependent on another patent. How we can give economic value to technology will also be based on the potentiality of its market and the existence of competitors. Likewise, as its valuation possibilities will depend, among others, on the possibilities to carry out complete and reliable market studies or the chances to focus its development on a product significantly different from its competitors'.

All said and done, the two terms are closely linked. At first contact with technology to be acquired, a price is assigned. The value of this price is based on different methods of access to technology that will be described in subsequent chapters. In the biopharmaceutical industry, continuous investment is usually required before the given technology even reaches commercial exploitation. A drug requires 10 to 15 years to reach the market, and the costs of continuous investment can add hundreds of millions of euros to the total costs of development. Nonetheless, the technology that supports the drug has the same value during the years in which it is in development. As certain milestones are met, the value of technology increases significantly. When a drug shows efficacy, passes toxicity tests or reaches clinical study – these are all very relevant milestones at which the technology in

question jumps in value. But if the milestones are not met, the value of technology can be reduced to zero. In other sectors, such jumps in the value of the technology are more linear and the technological risk is not random and therefore less difficult to predict. The value of technology therefore depends clearly on its expectations.

In this chapter binomial valuation will be discussed and illustrated through the valuation of a new treatment for a fictitious disease with a low prevalence rate. Binomial valuation refers to the valuation of technology, paying attention initially to determine the transaction price. Different mechanisms commonly accepted in technology valuation and biotechnology developments in particular will be reviewed to assess them and then consider how to value the technology acquired in early stages with the idea of retransmission at a higher price. The idea is to identify technology with potential; acquire it at a price that permits recovery; enhance it; and then transmit it at a higher price and/or exploit it.

Technology Assessment

The assessment phase of a technology is basically an assessment of its patents, and these have the potential to become products. Therefore, the main asset of the research centre is clearly the patent itself, which ultimately will be the asset of the transaction. In this section the different mechanisms of technology assessment will be reviewed to provide an example of a combined decision tree and discounted cash flow, which then leads to the development of hypotheses on how to value the technology.

Technology needs investments to be developed and finally exploited in the market. Its commercialisation also means assuming its most relevant costs for the company that exploits it, but there are sales costs associated to that, royalty or licensing agreements that revert in positive cash flows. Since the development of technology is associated with negative and positive cash flows, it is possible, in principle, to evaluate the technology in a given time, following certain economic criteria.

Additionally, technology is associated with technological risk, namely the possibility that at some point the technology will not prosper or not be robust enough to demonstrate results to market, or that at any given time it looks obsolete towards technology developed by competitors. The assessment of technologies should consider this factor: either introducing discount risk rates or decision-making patterns that envisage the event that the developing of the technology does not come to fruition. In the biopharmaceutical sector that is at hand, these considerations when evaluating technology become essential. The possibilities that technology in an early stage does not come to market are extremely high. Likewise, the possibility that technology could be superseded by the technology of a competitor is also high. At this stage in the first instance, acquiring technology requires the application of two things: (1) criteria to help diversify and/or mitigate risk and (2) resources to enhance the technology and bring it to a stage where it can be sold or licenced.

The risk is so high that it is common for the seller to share the risk of development assumed by the buyer of the technology. It is important not only to mention valuation models but also operating contracts that take into account the valuation of technology at the time it is sold and its future, entering into models of what might be called the “continuous assessment” of the technology.

The development of technology associates positive and negative cash flows, so an evaluation following economic criteria is often possible. If it is in early stages, the possibilities that it will not get to the market are extremely high, so seller and buyer both share the risk.

Below is a brief review of the different valuation models, followed by one illustrative example. We will rank some of the different valuation models based on their degree of complexity. Accordingly, every new method will include factors of the preceding one, according to a scheme where we incorporate the market potential of technology, the value of future economic flows, the possibility that these flows occur, the risk associated with the development of technology and finally the various options that allow the development of technology (licensing vs exploitation, or platform vs product, for example).

a. Methods Based on the Cost of the Patent

The licensing of technology at least wants to recover the costs invested in its development. It is a primary idea too often wielded in the case of the valuation of companies in early stages. To transmit the technology according to the amount invested until the time of its transfer has disadvantages for the seller and the buyer. The seller does not take into account the future value that technology can reach and therefore no part of the future flows. The buyer does not have to admit that technology has been developed properly and that what has been developed at a cost of two units could have been built investing, more efficiently, only one unit.

The cost assessment involves estimating the overall costs of developing technology to be licenced at the time. It will include investments, the costs of protecting intellectual property, the costs of staff involved in the research, etc. This system is not used because often times neither the buyer nor the seller has incentives to use it, except to set a minimum limit in a review as an argument (if there is a need to sell urgently) or to establish agreements based on the evolution of the technology where the costs system can allow establishing a down payment on the transfer of technology that will be complemented by further payments. Accounting is often the method chosen to evaluate the technology in the assessment of companies.

b. Assessment System Based on Income and Future Costs

As mentioned above, the development of technology suggests the establishment of a series of negative economic flows (the resources needed to exploit technology to the market) and positive economic flows (the income from the exploitation of technology). The accounting and valuation of these financial flows involves the participation of the seller in the future evolution of technology, understanding that the price of this depends on the potential that could be their future exploitation.

This is not to discriminate between the valuations of trading technology, although it is clear that both sides start from different positions in the ranking. The buyer will have to bear in mind the cost of future technology development, its potential for exploitation and the risk associated with the fact that it reaches the market. Therefore, to make an assessment based on income it is necessary to assess the market potential and investment needed to develop the technology. Earnings depend on market size and characteristics and multiple criteria must therefore be considered:

- The size of the market to target.
- The business model that supports this market, and develop, for example, whether the product will generate recurring sales, the type of commercial structure to be created, etc.
- The entry barriers to market access.
- Gross margin to be the product.
- The number and potential competitors.
- The penetration of the product on the market, its lifecycle and product obsolescence.
- The characteristics and commercial potential of the acquired company and its technology, ability / willingness to bring the product to market or proceed to their licence at a later stage.

The study of these factors not only yields a valuation of the price of a patent, but the same interest for the technology in question and the capacities to carry out a successful operation. The future earnings depend on the correct analysis of these data, allowing a set number of scenarios that allow us to establish an income account associated with the technology to develop, where revenues are the results of the exploitation of technology and costs, the costs necessary to carry out the operation.

Technology assessment based on the cost of the patent is rarely used because neither the seller nor the buyer benefits from it. An assessment based on income is preferable since it involves the valuation of the price of a patent, the interest of the technology itself and its potential for exploitation.

In the biopharmaceutical industry, R&D costs of technology and its commercial exploitation are usually well defined, given previous experience in the field with similar products. The development costs are associated with exceeding regulatory requirements to market a product. A drug must pass various concept, clinical stage and preclinical animal-people tests,

before receiving approval to be marketed by the authorities. The expertise acquired by the industry in terms of regulatory policies anticipates the characteristics of these tests that are aimed at developing the technology. In addition, the existence of large distributors in the industry identifies the costs associated with marketing, according to the countries in which it intends to distribute the product, the degree of penetration and sales efforts required.

To calculate the revenue, it is also possible to extrapolate data on existing products with similar features that are aimed at similar markets, while developing ad hoc hypotheses is also possible if the product does not have enough references. This way, a box can be built that allows the evaluation of the technology and in addition establishes a business plan to calculate the financial needs associated with its use.

Figure 4: (Illustrative example) *Market and income estimates*

General context: This example is based in a fictitious disease with a low prevalence rate and a potential treatment developped in the final stages of a Phase III Clinical Trial (commercialization to start in 2013). Since we assume the existence of competing treatments, none of the targeted countries have a penetration rate greater than 10%.

Calculation: Starting from an estimated number of patients, the study identifies the share of patients undergoing treatment by country. Once the total number of patients undergoing treatment is known, and making an approximation to the product price, it is possible to calculate the estimate of income.

Step 1 - Information from market (thousands of patients diagnosed)

	2012	2013*	2015	2018	2021
European Union (Big 5)	478,0	485,1	499,8	522,6	546,5
U.S.A.	465,6	472,6	486,9	509,1	532,3
Canada	51,5	52,3	53,9	56,4	58,9
Australia	31,6	32,0	33,0	34,5	36,1
Japan	201,9	204,9	211,1	220,8	230,8
Others	261,3	266,6	274,7	287,3	300,4
Total patients diagnosed (000)	1.489,9	1.513,6	1.559,4	1.630,6	1.705,1

Step 2 - Assumed the market share of the product (%)

	2012	2013*	2015	2018	2021
European Union (Big 5)	0,0 %	2,0 %	5,0 %	8,5 %	6,4 %
U.S.A.	0,0 %	1,5 %	3,6 %	6,5 %	5,5 %
Canada	0,0 %	2,0 %	4,5 %	9,5 %	8,0 %
Australia	0,0 %	2,0 %	4,5 %	9,5 %	8,0 %
Japan	0,0 %	0,0 %	0,0 %	3,6 %	6,4 %
Others	0,0 %	0,0 %	0,0 %	3,0 %	7,5 %

Step 3 - Calculate the sales volume or total number of patients treated (in thousands)

	2012	2013*	2015	2018	2021
European Union (Big 5)	0,0	9,7	25,0	44,4	35,2
U.S.A.	0,0	7,1	17,5	33,1	29,3
Canada	0,0	1,0	2,4	5,4	4,7
Australia	0,0	0,6	1,5	3,3	2,9
Japan	0,0	0,0	0,0	7,9	14,8
Others	0,0	0,0	0,0	8,6	22,5
Total patients treated (000)	0,0	18,4	46,4	102,7	119,7

Step 4 - Define a unitary average price for each market

	2012	2013*	2015	2018	2021
European Union (Big 5)	1,88 €	1,88 €	2,03 €	1,93 €	1,61 €
U.S.A.	2,44 €	2,50 €	2,70 €	2,57 €	2,15 €
Canada	2,21 €	2,27 €	2,46 €	2,34 €	1,95 €
Australia	2,12 €	2,17 €	2,35 €	2,23 €	1,87 €
Japan	2,20 €	2,24 €	2,33 €	2,50 €	2,63 €
Others	2,17 €	2,21 €	2,37 €	2,31 €	2,04 €
Average price	2,17 €	2,21 €	2,37 €	2,31 €	2,04 €

Step 5 - Calculate the market potential of the product (in thousand euros)

	2012	2013*	2015	2018	2021
European Union (Big 5)	0 €	18.241 €	50.729 €	85.736 €	56.750 €
U.S.A.	0 €	17.721 €	47.322 €	85.044 €	62.950 €
Canada	0 €	2.375 €	5.966 €	12.528 €	9.193 €
Australia	0 €	1.391 €	3.491 €	7.313 €	5.400 €
Japan	0 €	0 €	0 €	19.868 €	38.854 €
Others	0 €	0 €	0 €	19.941 €	46.002 €
Total sales (000)	0 €	39.728 €	107.508 €	230.430 €	219.150 €

**(Commercialisation starts)*

Figure 5: (Illustrative example) *Profit and loss account (P&L)*

Context: The example given involves significant human ressources and marketing costs associated to the project. Taking them into account, we can calculate the Project Contribution Margin (A). If we subtract the pending investment to finish Phase III (€35 MM in the example), we can recalculate the Project Contribution Margin including the full investment in clinical trials (B).

Step 1 - Calculate the gross margin of the product

	2012	2013*	2015	2018	2021
Total sales (000)	0 €	39.728 €	107.508 €	230.430 €	219.150 €
Average variable costs (COGs)	5,00%	5,15%	5,46%	5,97%	6,52%
Total variable costs	0 €	2.046 €	5.874 €	13.757 €	14.297 €
Gross margin (000 €)	0 €	37.682 €	101.634 €	216.673 €	204.853 €

Step 2 - Identify Fix costs (Marketing and human ressources expenses)

Marketing expenses

	2012	2013	2015	2018	2021
European Union (Big 5)	1.500 €	4.500 €	4.682 €	4.968 €	3.622 €
U.S.A.	0 €	2.500 €	2.889 €	3.589 €	3.239 €
Canada	0 €	250 €	331 €	503 €	468 €
Australia	0 €	175 €	220 €	308 €	296 €
Japan	0 €	0 €	0 €	675 €	579 €
Others	0 €	0 €	0 €	504 €	871 €
Total marketing expenses (000€)	1.500 €	7.425 €	8.121 €	10.548 €	9.075 €

Sales force expenses

	2012	2013	2015	2018	2021
Sales representatives full time dedicated					
European Union (Big 5)	10	60	70	40	25
U.S.A.	0	45	53	41	10
Canada	0	10	13	12	8
Australia	0	8	11	12	5
Japan	0	0	0	25	25
Others	0	0	0	5	7
Total sales force	10	123	146	133	80

Average cost for sale representative

European Union (Big 5)	125 €	131 €	145 €	168 €	194 €
U.S.A.	166 €	175 €	192 €	223 €	258 €
Canada	166 €	175 €	192 €	223 €	258 €
Australia	125 €	131 €	145 €	168 €	194 €
Japan	208 €	218 €	241 €	267 €	309 €
Others	130 €	134 €	143 €	164 €	186 €

Cost of human ressources (000 €)

European Union (Big 5)	1.250 €	7.875 €	10.129 €	6.700 €	4.848 €
U.S.A.	0 €	7.875 €	10.129 €	9.134 €	2.579 €
Canada	0 €	1.746 €	2.502 €	2.673 €	2.063 €
Australia	0 €	1.050 €	1.523 €	2.010 €	875 €
Japan	0 €	0 €	0 €	6.141 €	7.727 €
Others	0 €	0 €	0 €	0 €	1.300 €
Total human ressources expenses (000 €)	1.250 €	18.546 €	24.284 €	27.481 €	19.392 €
Total Fixed Costs	2.750 €	25.971 €	32.405 €	38.028 €	28.467 €

Step 3 - Calculate the project contribution margin (A)

	2012	2013	2015	2018	2021
Total fixed costs	2.750 €	25.971 €	32.405 €	38.028 €	28.467 €
A. Project contribution margin	-2.750 €	11.711 €	69.230 €	178.644 €	176.386 €

Step 4 - Calculate the project contribution margin including full investment on clinical trials (B)

	2012	2013	2016	2018	2021
A. Project contribution margin	-2.750 €	11.711 €	69.230 €	178.644 €	176.386 €
Investment in clinical trials (Phase III) + authorization to register (000)	35.000 €	0 €	0 €	0 €	0 €
B. Project contribution margin (with investment in clinical trials)	-37.750 €	11.711 €	69.230 €	178.644 €	176.386 €

Despite the obvious precautions that could be provoked by a method that aims to establish the current value of an asset with its projections of future growth based on assumptions that prove to be false, the assessment-based income and future costs provide many incentives to both the seller and buyer of technology. The seller, as mentioned above, as opposed to simple methods based on costs alone, can participate in future profits from the exploitation, and the buyer can determine the return on investment (ROI) – the acquisition cost of the technology – compared with investment alternatives. In addition, as does the biopharmaceutical industry, alternatives can be offered to the vendor to participate in future earnings of the business to negotiate delayed costs of acquisition. That is, in exchange for improving the current value of the patent for the seller, given the risk involved in its development, the buyer assumes lower investment, displacing and associating it to the achievement of goals that allow, for example, the attainment of additional resources.

Although taking into account the risks of this method of assessment, it is possible to highlight as key benefits that the seller will be able to participate in future profits from the exploitation, and that the buyer can determine the return on investment (ROI) and displace investment in association with future goals.

Either way, a loss and profit account it is not sufficient to establish the value of technology. It lacks discounting the values of the future cash flows to establish the actual value of the technology (discounted cash flows criteria). Additionally, being technologies with a high return and a high risk of failure, it lacks establishing policies, such as the decision-making patterns that allow evaluating several scenarios (for example in the biopharmaceutical industry, the possibility that a product does not passes clinical phase II or the fact that the product competes with an alternative technology). This second method, the assessment by a decision-making pattern, is no different than applying a greater discount rate in a discount cash flow system, but in the biopharmaceutical industry, it is worth separating them so that the assessment used not only serves to set the value of the product but also allows it to guide the negotiation process.

The assessment by the principle of discounting cash flows due to the criterion of the evolution of a currency over time, with preference to present a stream of future cash flow, unless they are seen by an increased differential that is called the *interest rate*. The interest rate applied to the discount will depend on the performance required of the asset, which in turn will depend on the rate of risk. Therefore, the expected return from a technology development will be higher the riskier the development is. A drug can have a huge potential market, but the patent protecting this product at the end of its initial phase, when the chances of reaching the market are one in one hundred and the necessary investments equal millions of euros, may imply lowering its value. The explanation relies on the discount rate applied and the technological risk inherent to their development.

The net present value (NPV) of a technology is, therefore, the result of a discount rate risk given the flows of income and gains from technology, and it is calculated through a financial formula. Taking the example above and a discount rate of 15%, we would encounter the following value:

Figure 6: (Illustrative example) *Calculation of current value at 15% discount (thousand euros)*

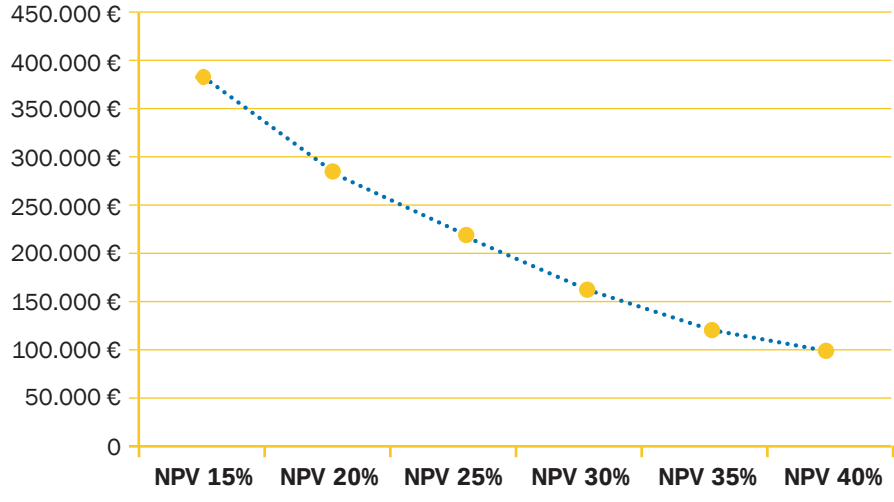
2012	-37.750 €	**2017**	152.947 €
2013	11.711 €	**2018**	178.644 €
2014	35.999 €	**2019**	187.773 €
2015	69.230 €	**2020**	180.314 €
2016	109.604 €	**2021**	176.386 €
NPV 15%			383.296 €

The choice of the discount rate is key in achieving the final assessment.

Leaving the method discussion aside, once accepted, the negotiation to agree on a price for the valuation is based on agreeing on a discount rate, usually to lower levels when the seller speaks (arguing a lesser risk of the project) and to higher levels when the purchaser rebates (asserting the higher profit of the project). A value appropriate rate is the weighted cost of capital, requested that the asset is held to the same as the average cost of the project. In a biotechnology company, for example, financed by venture capital and having acquired a licence for a technology, this cost is not less than 15% of the previous example. In the chart below, which is based on the hazard rate, the elasticity of the valuation of companies can be seen:

Figure 7: (Illustrative example) *Different current values associated with different discount rates (from 15% to 40%) (thousand euros)*

2012	-37.750 €	**NPV 15%**	383.296 €
2013	11.711 €	**NPV 20%**	283.122 €
2014	35.999 €	**NPV 25%**	212.200 €
2015	69.230 €	**NPV 30%**	161.010 €
2016	109.604 €	**NPV 35%**	123.406 €
2017	152.947 €	**NPV 40%**	95.339 €
2018	178.644 €		
2019	187.773 €		
2020	180.314 €		
2021	176.386 €		



Although the cost of financing does not exceed 15% in the biopharmaceutical sector, the discounted cash flow system does not consider an obvious fact. The possibility of a technology that does not exceed certain targets is high, and overcoming them may involve reducing its value to a hundredth of the cost of development. Consider whether a technology that has only a 10% chance of reaching the market can have a value as proposed in the above table, despite the figures of expected revenue. In any case, technologies like those above, purchased together, could achieve this value, hoping that statistically, at least one of them will achieve compliance with the business plan as scheduled in the income statement. Assessing technology only by discounting the flows at a determined rate does not consider the possibilities that a technological project may continue forward or fail. When the phases in a project being developed are known to be narrowed, and when it is statistically possible to anticipate the choices of success or failure in achieving a goal, the assessment mechanisms for using a discounted cash flow tree of possibilities are complete.

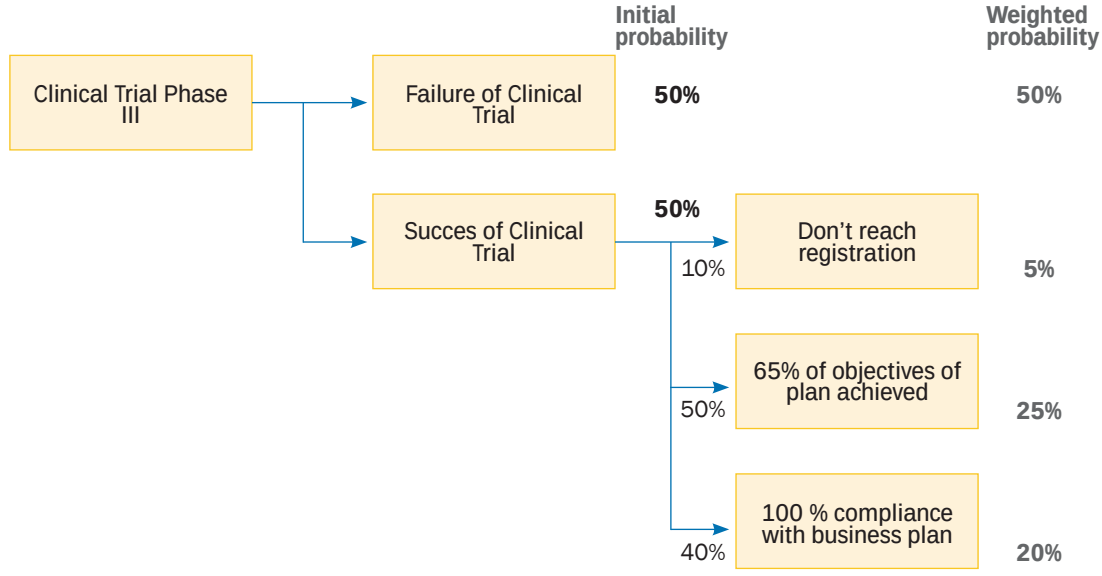
The discounted cash flow based on a tree of possibilities takes into the consideration the possibility that a technological project may continue forward or fail.

This system can easily be set for a given point in the development of technology alternatives, each with a particular stream of revenue and expenditure. Each of these possibilities has a statistical prob-

Figure 8: (Illustrative example) *Table of chance events*

General context: This example is based in a drug reaching the final stages of Phase III Clinical Trial including a significant number of patients, and contains potential statistically different scenarios to be considered.

Calculation: The probability ratio of finishing the full Clinical Trial successfully is only 1 over 2, since the trial has a 50% probability of failure (i). Once that milestone has been achieved, the probability that the product does not reach commercialization is 10% (ii). In 50% of the other scenarios, we will only reach 65% of the proposed plan objectives (iii) and in the other 40%, we will fully meet the objectives (iv). Therefore, the weighted probabilities of each scenario are (i) 50%, (ii) 5%, (iii) 25%) and (iv (20%).



ability, and the net present value of the technology with this calculation is the sum of net present value of the different alternatives available. The following example also concerns the evaluation of a drug that is about to begin clinical trial III.

The possibilities of failure in the clinical trial in this case amount to 50%. If the drug does not pass this test successfully at the same value, it will be reduced to the value of the data obtained in previous tests. With a little luck, it may have new applications, and, having demonstrated toxicity in previous phases, it would be a second chance. This brand can double the value of the technology, but even if the trial has some success, the results would lead to different scenarios. In the table, there is a first, disastrous result, where regulatory bodies do not grant registration. This possibility is assigned a 10% chance (5% is weighted with the success of the trial). Additionally, compliance with the business plan is proposed, and thus meeting the expected cash flows (positive and negative) or the performance of only 65% of the business plan, including expected lower investments in marketing, because the market was not as receptive as expected or perhaps due to the presence of more competitive products.

The alternatives presented allow for consideration of different possible scenarios of cash flow, taking into account some peculiarities. For example, in the case of failure of the clinical trial, the only investment will be reduced to the costs of the trial, because it does not assume the costs of health registration and obviously does not assume the investment necessary for marketing. Using the method of the decision tree, each weighted by the probability of economic flow, a *risk-adjusted* economic flow is obtained. Deducting this flow by a hazard rate of 15% results in a net present value adjusted to technological risk, in the example, relating to clinical trial III.

Using the method of the decision tree, each weighted by the probability of economic flow, a *risk-adjusted* economic flow is obtained.

Figure 9: (Illustrative example) *Calculation of risk-adjusted net present value over the project's contribution margin, taking into account the proposed decision tree*

Step 1: Assign an economic cash flow to each scenario

1. Failure of clinical trial Phase III,
2. Successful trial without registration,
3. 65% of objectives achieved and
4. 100% of objectives achieved depending on the weighted probability of each scenario.

In order to carry out this task effectively, a subjective approach must be taken. For example, in scenarios 1 and 2, only the cost of the Phase III trial should be included, excluding the rest of costs related to registration or commercialization. That is because upon failure, we will not have to execute the rest of the planned investments like marketing and human ressources costs starting 2012.

Step 2: Calculate the cash flows by applying the weighted probabilities calculated on figure 8. Discount the flows to a previously determined discount rate, related to the financing cost of the project. In the example, we have used 20% since we consider that a great deal of the project will be financed through equity. The resulting number is the NPV of the project.

	2012	2013	2015	2018	2021
A. Project contribution margin (without clinical trials Investment)	-2.750 €	11.711 €	69.230 €	178.644€	176.386 €
Investment in clinical trials (Phase III) + authorization to register (000)	-35.000 €	0 €	0 €	0 €	0 €
1. Failure of Clinical Trial (Phase III) (only Clinical Trial investment)	-17.500 €	0 €	0 €	0 €	0 €
2. Sucessful trial without registration (only Clinical Trial investment)	-1.750 €	0 €	0 €	0 €	0 €
3. 65% of objectives of Plan achieved (clinical trial investment + 65% Business Plan)	-9.197 €	1.903 €	11.250 €	29.030€	28.663 €
4. 100% compliance with business plan	-7.550 €	2.342 €	13.846 €	35.729€	35.277 €
Operating profit adjusted for risk	-35.997 €	4.245 €	25.096 €	64.758€	63.940 €
Discount rate	20%				
NPV Project	84.038 €				

Even at an equal rate for each of the resulting flows, once the Phase III cost of access to capital can be reduced, for example, different scenarios are yielded. The decision tree method allows more flexible planning, is appropriate to the situation and the present value of technology and, as discussed below, may also allow use in licensing agreements.

The discounted cash flow method based on a decision tree can evolve to more complex systems such as real options, initially developed to calculate the value of financial options but perfectly usable for evaluating technology. As in the case of financial options, where you can sell a particular asset at a certain price or buy it (in the case of a purchase option), a technology option gives its owner a given amount of time, graduating from the new technology, initiating the development and/or marketing, or for such a specific technology or another. The approach of this method is similar to the tree of possibilities, but the real options require more complex mathematical models to be used. The method of real options requires a dynamic assessment of technology, as when a decision was possible to evaluate new technology, applying different rates to more risk. Despite its realistic approach to the evolution of technology, it has the disadvantage of its complexity and the need to raise a greater number of scenarios than in previous methods.

Negotiation of the Valuation

The assessment of technology at the heart of a retail business licence is related to the price of this transmission and therefore is subject to a negotiation process where the buyer and seller defend hypotheses to reach the most satisfactory price or what would be considered a fair transaction. As mentioned earlier, the valuation of future income through technology allows the seller to share in the future value of technology, which is incremental as certain goals are met. In the biopharmaceutical industry, licence agreements typically use mechanisms of this type, but

only to calculate the value of an asset not to postpone the necessary investments for its acquisition.

An assessment of the technology of a pharmaceutical product in early stages involves estimating, using trees of possibilities, scenarios where the risk of failure is very high. In this context, the negotiation for the purchase price of patent mechanisms logically lead to agreements on payments associated with a transaction that is delayed until reaching certain goals. The reason is two-fold. On the one hand, the seller of the technology increases the net present value of it, giving up an immediate income. The value of the sale, thus, can be increased significantly if the buyer cannot immediately pay the value of the technology, as is the case of many technology companies in early stages of development, which are the engines of technology transfer. On the other hand, the buyer accepts to sharing the future benefits accrued by the technology, but only if the development of the technology achieves the objectives, allowing the generation of income or "providing value" to the technology.

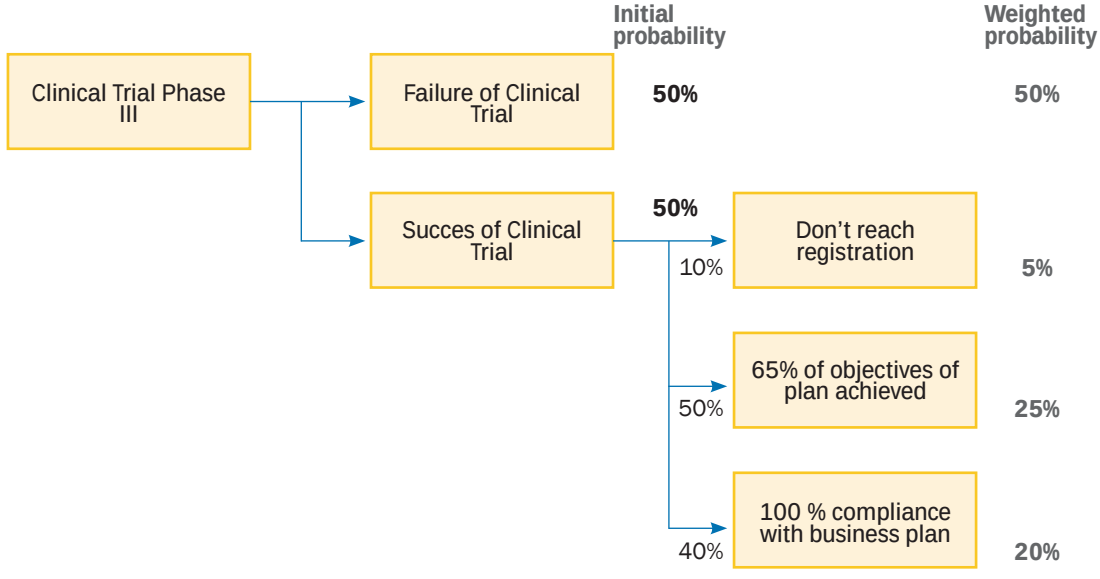
Given the intrinsic risk associated to the acquisition of technologies in early stages of development, it is reasonable to incorporate it in the purchasing negotiation process and delay payments until reaching certain goals.

The negotiation process to reach this agreement, which is typical of technology licensing in early stages and thus closer to the subject of this guide, depends on various factors. The above example was used to illustrate these factors. It is a stage of negotiation based on the license of a drug before starting Phase III. The investment needed to achieve this value is 35 million euros, and the tree of possibilities, as was used.

Figure 10: (Illustrative example) *Table of chance events*

General context: This example is based in a drug reaching the final stages of a Phase III Clinical Trial including a significant number of patients, and contains potential statistically different scenarios to be considered.

Calculation: The probability ratio of finishing the full Clinical Trial successfully is only 1 over 2, since the trial has a 50% probability of failure (i). Once that milestone has been achieved, the probability that the product does not reach commercialization is 10% (ii). In 50% of the other scenarios, we will only reach 65% of the proposed plan objectives (iii) and in the other 40%, we will fully meet the objectives (iv). Therefore, the weighted probabilities of each scenario are (i) 50%, (ii) 5%, (iii) 25%) and (iv (20%).



The current value of this project, in the example, is 84 million euros for the buyer of technology, which will cover later investments. The assessment of the technology when applying discount rates that give as a result very high returns, results in much lower values, in which case the key of the agreement is to share the actual value of the technology with the generator of the technology. At this stage, it is common for the originator of the technology to hold between 30% and 50% of the value given to the project, which provides the buyer with an agreement for payment of 20% of this amount and a series of payments are made at the time variables according to established milestones. Here an upfront payment of 4 million euros was proposed with 6 million euros once Phase III is completed and an additional 10 million euros once the product is registered. Note that payments are associated with compliance targets that act as a vertex in the decision trees. Thus, the calculation of future flows for each of the possibilities is adapted to calculate the present value weighted in simple technology.

Figure 11: (Illustrative example) *Payment proposal associated to milestones and impact on the contribution margin*

The buyer assumes the milestone payments as well as the cost of finalizing the clinical trial.

	Proposal of payments according to milestones	Licence fees (000)	Year of payment
Down payment	20%	4.000 €	2012
Payment to reach Phase III	30%	6.000 €	2013
Comercialization (Registration)	50%	10.000 €	2014
TOTAL		20.000 €	

	B. Project contribution margin (with investment in clinical trials)	Milestones	C. Contribution margin Project (with investment in clinical trials & milestones payments)
2012	-37.750 €	-4.000 €	-41.750 €
2013	11.711 €	-6.000 €	5.711 €
2014	35.999 €	-10.000 €	25.999 €
2015	69.230 €	0 €	69.230 €
2016	109.604 €	0 €	109.604 €
2017	152.947 €	0 €	152.947 €
2018	178.644 €	0 €	178.644 €
2019	187.773 €	0 €	187.773 €
2020	180.314 €	0 €	180.314 €
2021	176.386 €	0 €	176.386 €

Additionally, a royalty is calculated based on a percentage fee of the sales, which the buyer pays the seller. In the example, the amount of these royalties is 15%, calculated so that the net present value for the seller is equivalent to 35% of the net present value of the project, and the buyer gets the remaining 65%.

Figure 12: (Illustrative example) *Proposed allocation of royalties*

The 15% royalty expressed in the example is inherently part of the agreement between both parties. In the example, both parties agreed that the seller would retain 35% of the value of the project and therefore agreed to the percentage of royalties that, under the explained economic scenarios, would yield such distribution.

	2012	2013	2015	2018	2021
C. Contribution margin project (with investment in clinical trials and milestone payments)	-41.750 €	5.711 €	69.230 €	178.644 €	176.386 €
Total Sales	0 €	39.728 €	107.508 €	230.430 €	219.150 €
Royalties for originator (% of gross sales)	15,00%	15,00%	15,00%	15,00%	15,00%
Total royalties	0 €	-5.959 €	-16.126 €	-34.564 €	-32.873 €
D. Contribution margin Project (with investment in clinical trials, milestone, payments and royalties)	-41.750 €	-248 €	53.104 €	144.080 €	143.513 €

Figure 13: (Illustrative example) *Impact of royalties and payments associated with the process of negotiation in the current value of the project*

Build a table to calculate the distribution of the project's value between the parties involved. The result is the NPV for the buyer. Similar to the case of the decision tree valuation detailed earlier, the approach to these weighted flows should be subjective. In the case of failure of the Clinical Trial, for example, the buyer will only assume the first down payment and the cost of the trial. However in the case of successful trial without registration, the buyer will have to assume the second down payment to the seller, since even though the product is not yet commercialized, the product has in fact successfully reached the end of the Clinical Trial. In the scenarios of partial and full achievement of objectives, the flows are calculated taking the weighted probability of each scenario, as before.

	2012	2013	2015	2018	2021
A. Project contribution margin (without clinical trials Investment)	-2.750 €	11.711 €	69.230 €	178.644 €	176.386 €
Investment in clinical trials (Phase III) + authorization to register (000)	-35.000 €	0 €	0 €	0 €	0 €
Milestones	-4.000 €	-6.000 €	0 €	0 €	0 €
Total Sales	0 €	39.728 €	107.508 €	230.430 €	219.150 €

Figure 13: (Illustrative example) *Impact of Royalties and payments associated with the process of negotiation in the current value of the project (CONT.)*

Royalties for originator (% of gross sales)	15,00%	15,00%	15,00%	15,00%	15,00%
Total royalties	0 €	-5.959 €	-16.126 €	-34.564 €	-32.873 €
D. Contribution margin Project (with investment in clinical trials & milestone payments & Royalties)	-41.750 €	-248 €	53.104 €	144.080 €	143.513 €
Failure of Clinical Trial (Phase III)	-19.500 €	0 €	0 €	23.413 €	0 €
Successful trial without registration	-1.950 €	-300 €	0 €	28.816 €	0 €
65% of objectives of the Plan achieved	-6.784 €	-40 €	8.629 €	23.413 €	23.321 €
100% compliance with business plan	-8.350 €	-50 €	10.621 €	28.816 €	28.703 €
Operating profit adjusted for risk	-36.584 €	-390 €	19.250 €	52.229 €	52.024 €
Discount rate	20%				
NPV Project (65% of previous NPV)	55.251 €				

The seller uses the same discount rate as the buyer and the same tree of possibilities to calculate the net present value. Therefore, if the project is successful, the seller will enjoy a very high rate of return, increasing the return compared to that if the transaction had been made on a single payment (although initially the net present value is the same). The buyer will only have to deal with these payments if the project succeeds. The outcome of these negotiations is that both parties are linked to the success of the project and therefore have an incentive to focus their efforts on its development.

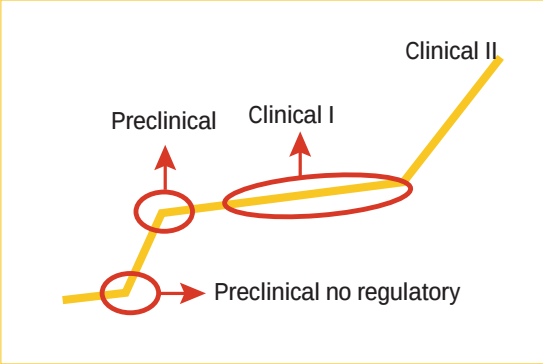
Both the seller and the buyer base their negotiation on the same parameters (discount rate and tree of possibilities) and will obtain high benefits from a successful development (*win-win* negotiation).

Recovery

Technology increases its value as certain goals are met. In the biopharmaceutical sector, this statement gives meaning to the business model of the sector, as investment in the technology development is compartmentalised and regulated in different stages. The successful completion of any of these stages involves a revaluation of the technology.

Strategies for recovery of scientific results are a useful mechanism for profitable research. The recovery is to increase the value of these results in order to promote technology transfer and ultimately increase the price of the transaction. Recovery depends on the phase in which the technology is; evaluating the technology in early stages may involve simply devoting more resources to the strategy of protecting intellectual property, while in later stages it can be reduced to correctly choosing a particular application for the technology. This makes it difficult to write about recovery and propose specific procedures, but ultimately, enhancing technology can be summarised as an investment of time and money. The key to making a successful recovery is to propose actions that require less time and fewer resources required for the technology to reach its maximum value.

Figure 14: Value increase based in Proof of concept



The effective completion of any of the biopharmaceutical development stages involves a revaluation of the technology. Successful recovery implies proposing actions to maximise value with the fewest resource in the shortest period of time.

In an industry where every euro ingested would involve a further Euro Appreciation, there would be little space to talk about valorisation. However, as the upgrades in value are discrete pursuant to the results of the research, protecting of the technology or simply undertaking a good market survey, we can start thinking of giving priority to those actions that will allow us to undertake such an upgrade. We must differentiate the concepts of *recovery* and *maturity* of technology, as they can lead to different decisions. While maturity involves covering all phases of a project to place it on the market, recovery involves specific strategies, always focused on the transaction, inside maturity.

It is in the early stages of the technology when valuation makes more sense, as the strategic options are wider. This is usually the scenario in which there is technology transfer – not only technology developed beyond proof of concept – between academia and the company. When technology is transferred, the options are numerous, including the possibility of improving the patent. In fact, recovery in this phase begins with the ability to track the scientific and technological environment for technologies that are innovative, protected (or that may be protected) and that respond to the needs of the market, as mentioned above, but also that are valuated efficiently and cost effectively. In fact, this assessment should be completed with the divestment strategies related to technology, evaluating whether it is possible to transfer it or sell it quickly or if the recovery requires a long-term plan. That is, it can include discarding different technologies, picking one that might be less protected or holds a smaller market potentiality, but that it is easy to package or faster to licence. *Packaging* means enhacing value by providing technologically specific actions, by definition cheap and which require little time. This is to make a *package* sale of technology that makes it attractive to the market. Therefore, *packaging* implies the idea of moving from technology, the output of the academic group, a product, which is what the market requires, namely:

- Passing an initial technology to a developed technology.
- Moving away from a technology market without a clear application in a technology-oriented market and a specific product.
- Moving from a technology without intellectual property market strategy, to a packaged technology, and design the necessary experiments to improve the degree of protection and demonstrate their efficiency.
- Moving from a detached technology industry to a technology with a production plan that takes into account concepts such as productivity and scalability.

The most notable impact on recovery experienced in this phase is when the technology is subject to a proof of concept in relation to its effectiveness. Here strategies called IP Driving Research (research aims) are discussed, which without abandoning the term research, intend to target the research only to those research activities that generate more value for the project, especially those designed to solidify the position of intellectual property. The IP Driving Research focuses on conducting experiments that sustain, one by one, the claims that construct the patent, with the objective of providing more solidity, for example, when requesting the patent PCT, as it is possible to provide additional documentation. According to the previous chart, we can see how the technology is in-

creased significantly in value when it has passed a successful proof of concept.

Short recovery requires time and resources in the form of investments, but this may mean that the value is multiplied by the simple effect of reducing technical (and commercial) risks for the potential licencee of the technology.

The Role of TTOs in the Protection of Technology.

The fundamental aim of TTOs is the transfer of technology from research centres to the private sector. Its activity can be defined as commercial, since its objective is to find a "buyer" for these technologies through different mechanisms of transfer: sale, licensing, spin off, etc.

The raw material of the TTOs is the technology developed by the centres. For this reason, as explained in this chapter, the possibility of transferring this technology is necessarily based, in its initial state, on adequate protection of the technology assets they manage.

All the regions participating in the INTERBIO program have different TTOs associated to each group / research centres. In many cases (Barcelona, Valencia, Toulouse Region), each centre has its own transfer resources, while in others (Aquitaine) one TTO concentrates and manages all resources managed from different research centers. The TTO concentrates much of its resources on identifying technologies that can be transferred and they promote prior to their licence, in most cases, processes of protection of technology, through patent applications. In Valencia, for example, the TTO of the University of Valencia has a portfolio of over 140 patents, while the Polytechnic University of Valencia publishes an annual average of 20 to 25 patents. In Toulouse University the number of patents managed by all the TTOs is more than 700 patents, publishing annually more than 70.

Quick Guide for assessment and recovery of technology

ASSESSMENT AND RECOVERY OF TECHNOLOGY

QUESTION 5. IS THE TECHNOLOGY WORTH?

Key Issue: Understand the difference between three closely related terms

Assessment: assign a value to a product or technology. The assessment of technology is basically the assessment of its patents and it's foreseeable capacity to generate future incomes.

- Incorporating economic criteria for its evaluation: development of a technology is associated with negative (resources needed) and positive (income from exploitation) cash flows.
- Taking into account technological risk through discount risk rates or decision-making patterns (e.g. milestones and continuous assessment)

Recovery: perform the tasks necessary to increase the value of the technology in a given period of time, in order to promote technology transfer and ultimately, increase the value of the transaction. In early stages may involve simply improving IP strategy, in later stages choosing an application for the technology.

Maturity: covering all phases of a project to place it on the market. Recovery involves specific strategies focused in the transactions, inside the maturity.

Quick Guide for assessment and recovery of technology *(CONT.)*

ASSESSMENT AND RECOVERY OF TECHNOLOGY

Key Issue: Assessment - Choose the method to assess its value and maximize recovery (listed according to degree of complexity. Illustrative example based on pharmaceutical industry in corresponding Chapter 2C)

Methods based on the cost of the patent: the licensing of a technology leads to the recovery of the costs and investments undertaken by the licencee in the development of technology. Scarcely used except in urgent operations or calculation of initial down payment.

Advantages: Minimum cost of transaction for the promoter. The investment cost is usually used as a minimum purchase price sale.

Disadvantages: The seller does not consider the future value that technology can reach, which also means part of the future flows. The buyer does not have to admit that the technology has been developed properly.

Assessment system based on income and future costs: assigning a value to the current negative and positive economic flows associated with development and exploitation of technology

- Analyse and build scenarios based on
  - **the market** to be entered (size, competitors, entrance barriers and business model accepted),
  - **the future product** (expected gross margin and market penetration, its life cycle and product obsolescence) ,
  - **the acquired company** (potential ability / willingness to bring the product to the market/licence it).

Advantages:

- The seller participates in the future profits of exploitation.
- The buyer can determine the ROI (Return on Investment for acquiring the technology) in comparison to alternative investments.

Disadvantages:

- Assessment based on assumptions that if proven to be false will create instability and unreliability.

Complications:

- Determine discounting the values of future cash flows to establish the actual value (Net Present value, NPV).

Rating system based on tree of possibilities: Incorporate decision-making patterns that allow the evaluation of several scenarios. The successful completion of any of the stages involves a revaluation of the technology (recovery).

- Complete evaluation mechanisms for discounted cash flow through a tree of possibilities, when the probability of success of the different phases in a project being developed are known and can anticipate statistically options of success or failure of each milestone.
- Allows more flexible planning
- May evolve to more complex models: evaluation by real options.

Advantages: Allows the assessment process associated with the contract transaction, involving future payments in the evolution of the value of the company. (See section "Negotiation of the Valuation")

Key Issue: Negotiate the valuation of the technology

Negotiation of the valuation: negotiation process where the buyer and the seller defend the hypotheses to reach the most satisfactory price or what would be considered a fair transaction.

The purchase price of a licence in early stages of a product development, where the risk of failure is very high, is usually linked to payments associated to the achievement of goals (milestones), and these, to an increase of value of the product.

A royalty may also be agreed, and calculated based on the percentage fee of the sales which the buyer pays de seller.

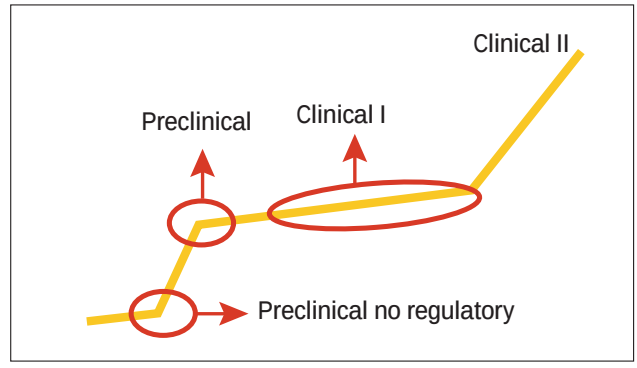
The seller uses the same discount rate as the buyer and the same tree of possibilities to calculate the NPV. Therefore, if the project is successful, the seller will enjoy a higher rate of return compared to that if the transaction had been made on a single payment.

Quick Guide for assessment and recovery of technology *(CONT.)*

ASSESSMENT AND RECOVERY OF TECHNOLOGY

Key Issue: Recovery - increase the value of the technology

Recovery in early stages: "package" technology in early stages to multiply the possibilities of and increase the transaction price



- **Packaging:** enhance value by providing technologically specific actions, cheap and fast. Complete the assessment with the divestment strategies, evaluating whether it is possible to transfer it or sell it quickly or if the recovery requires a long-term plan.
- **IP Driving Research** (research aims), conducting experiments that sustain one by one the claims that construct the patent. Acquire technology with a defined regulatory package, the design of experiments necessary to improve the level of protection and demonstrate effectiveness.
- Targeting the right technology to the market, and a specific product.
- Strategy for the protection of intellectual property.
- Develop a production plan that takes into account concepts such as productivity and scalability.

D. TRANSFER OF PUBLIC RESEARCH RESULTS TO THIRD PARTIES: AGREEMENTS THROUGH LICENCES

Whenever a new result of the investigation is generated, and provided that the entity that created it is not interested in exploiting it (either directly or through the creation of a spin-off), the possibilities of transferring the rights to a third party will accrue.

The need to generate new business opportunities has made the transfer of technology the main objective of research centres, especially those in the public sector. This has created new policies to regulate these processes in order to develop this

activity, allowing the centre to defend its interests at all times.

To this end, we can define technology transfer as all those agreements, irrespective of their legal status, which allow a relevant individual to obtain rights over knowledge, works and inventions created by another[7].

In relation to this matter, the European Commission proposes the following recommendation:

> *'11. Develop and publicise a licensing policy, in order to harmonise practices within the public research organisation and ensure fairness in all deals. In particular, transfers of ownership of intellectual property owned by the public research organisation and the granting of exclusive licences should be carefully assessed, especially with respect to non-European third parties. Licences for exploitation purposes should involve adequate compensation, financial or otherwise."*

The European Commission is considering, as a way of granting a preferential transfer right, a licence agreement, by means of which the centre maintains ownership of the technology but gives the company a right to use and exploit it (usually exclusively) so that it can be marketed.

However, a full transfer of technology may also operate, so that the company should become the sole owner (without prejudice to the personal rights that apply to authors and inventors), and may freely relate the technology in their activities.

Both formulas allow the company to hold full authority for the use and exploitation of technology for its business. However, the grant of a licence allows greater control to the centre for the protection and exploitation of such technology.

The technology transfer involves all agreements which allow an individual to obtain rights over knowledge, works or inventions created by another, and can go from transferring certain rights (use, exploitation) to the full transfer, where the purchaser becomes the sole owner.

In any event, the grant of exploitation rights will require the subscription of an agreement regarding the transfer of the research results, in which they should follow the procedure of awareness established by law.

To this effect, this chapter will analyse the steps in the negotiation of an agreement regarding the transfer of research results.

Preparation and Negotiation: A Procedure for the Award

The first thing to be considered is the procedure to be applied in transferring research results to a company. This will be particularly important in the case of public research centres, due to any applicable legislation that regulates public property.

In this regard, certain regulations (e.g., the Law of Sustainable Economy in Spain) establish the guarantee of an award granted on a competitive basis, i.e., by allowing several companies to participate in the process and to place their offer[8].

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[7] Costas, I., Griffiths, A., Ouro, A. "Guía de Transferencia de Tecnología de Centros Públicos de Investigación para las Empresas", Instituto Tecnológico de Canarias, 2009.

[8] BIOCAT: "The recent Sustainable Economy Act approved a procedure for Universities and research centres of the Spanish administration. This regulation provides that the transfer must be from a competitive bidding process in which advertising is guaranteed (by the website of the institution) and the award to the most economically advantageous tender.
This regulation is not, in principle, applicable to the centres in the Autonomous Communities. Catalonia has approved a law allowing autonomy to research institutions to establish their own procedures for transfer of technology, without having to follow the general administrative rules."
ITQB-UNL: "There are legal procedures, but they are not totally established. Intellectual Property Codes have been approved in many Universities, but implementation of the processes is still in development."
Aquitaine Valo: "No legal procedure exists. The transfer of technology is based on an OTC (over the counter) contract that respects the IP legal code."

This is a formula that, firstly, ensures greater transparency and objectivity in determining the company that will commercially exploit the research results, but at the same time may not be consistent with the needs of confidentiality that the nature of the business may require. Nonetheless, a relatively open bidding process would put sensitive information about the technology on a public format, keeping in mind that the placement of innovative input of technology out on the market could - in the end – undermine its future competitiveness.

Depending on the rules applicable to a given scenario, competitive bidding procedures tend to follow these steps:

- Advertising: first, publicity is given to the existence of the research results and to the possibility of exploiting them commercially. Depending on the procedure, the publication may have a general range, or be limited to certain entities that are considered appropriate by the centre concerned.

  To this end, one of the most common ways to be followed is the Pool of Patents, which allows research centres to announce publicly the available research results.

  In other cases, the publications and calls for research results may have a more individualised character.

  In addition to the data regarding the research results, the publication may contain conditions to be met by the companies and the criteria on which the award will be based.

- Submission of applications: interested companies must submit their proposals adjusted to the conditions required by the centre.

- Award: finally, the centre, after acknowledging that all conditions have been met, will decide which proposal best meets their criteria, which may consist solely of economic conditions or may also include other requirements of a technical nature.

Whenever there is no competitive bidding procedure for the award of the agreement, both parties may negotiate its terms freely, without the need of a specific procedure.

When starting a transfer of technology agreement, the first element to be considered is the procedure to be applied according to the type of institution: competitive bidding or private scheme of negotiation.

In this case, there is a need to adjust to a private scheme of negotiation, without publication requirements, that could contain the following steps:

- Non-Disclosure Agreement: as a technology analysis will be required in the procedure, the centre will want to have ways of ensuring that the information the company can obtain in the negotiation will not be used for any other purpose than the assessment of the operation (and in particular, that it cannot be used afterwards by the company without authorisation from the centre).

  Therefore, both parties may enter into a non-disclosure agreement, which may have a unilateral structure (one of the parties will have to adhere to the document proposed by the other) or bilateral (agreement between the two parties).

- Prior Negotiation (Letter of Intent): to frame the negotiation, the parties may sign a letter of intent, detailing those previous agreements already reached and the rules that shall govern the negotiation.

  Their contents and effects depend on the circumstances of each case, but the following topics may be included:

  – Initial covenants to start the negotiation

  – Schedule of the negotiation (including whether it can be extended or not) and the terms that shall govern it

  – Exclusivity in the negotiation

  – Allocation of the expenses arising out of the negotiation process

  – Guarantee for non-compliance

- Technology Audit: after securing confidentiality undertakings, the company or the relevant experts appointed may verify the technology or knowledge presented, to check features and functionalities, and, where appropriate, the innovative character (in particular, if no patent right has been applied).

- Negotiation: finally, the parties will negotiate the terms for transferring the rights to the research results, which ultimately will be transposed into the contract of transfer of technology, and in which each party will seek to defend its main interests:

  – For the company, to secure a right to use and exploit the results of the research to the fullest extent possible (in terms of geographical and material coverage) and with the best economic conditions.

  – For the centre, particularly when it is of a public nature, to provide maximum social dissemination of the research (in view of their public interests) and to reserve the possibility to continue their research without prejudice, so that in accordance with public policy, a proper economic consideration for the transfer shall be obtained.

The Transfer of Technology Agreement

This is the document that will govern the grant of the rights by the centre to exploit the technology or the knowledge in the general market.

Additionally, the research centre usually retains a series of powers to protect its interests (and the public's interests when it is publicly owned) in the exploitation of the technology, and also promotes its effective exploitation based on a criterion of spreading capabilities[9].

The list of clauses that may be used in a transfer of technology agreement is very broad, and the actual clauses used will depend on the specific circumstances of each scenario. However, generally they tend to be the following:

The second key element is the elaboration of the cooperation agreement, which should include: terms and conditions of the transfer, compensation, rights on developments and technology improvements, provisions for the protection and defence of the technology, assumptions of liability and indemnity and protection of the public interest.

[9] Aquitaine-Valo: "It depends on the kind of agreements, but research institutions generally share the risk with the companies in order to share the costs. Here are two cases:
- Techno push approach (spin-off or licensing out): the research institutions generate alone the first IP rights and the companies receive exclusive or non-exclusive exploitation licences to improve, develop and commercialise the invention.
- Market pull approach: the IP rights are shared according to the respective financial support of each partner.

Usually, research institutions seek to keep the rights to publish their results. Sometimes the IP rights are assigned to the company if researchers are allowed to continue their research activity outside of the IP field."
BIOCAT: "In general, public research centres reserve powers to protect their legal position and the public interest in the exploitation of research results. They can reserve powers to protect the results, such as monitoring of the protection process or the assumption of defence against violations or claims of third parties.
In the economic field, in addition to the compensation due, a clause is usually reserved for a better life, to participate in the benefits of future transmissions.
And regarding the exploitation, public school faculty may reserve a reversion of rights, in case of disuse or use contrary to the guiding principles.
In the case of creating a spin-off, in addition to the foregoing rights, two main types of power are reserved: (i) relating to the management of the company (composition and functioning of the organs of government and representation, adoption of strategic agreements), and (ii) with respect to the transmission of participation (right of first refusal, tag along, right out)."

- **Terms and conditions of the transfer of technology**

  First, the kind of transfer to be used must be defined (usually a licence, although it may also be achieved by assigning full rights over the technology), and whether to grant it on an exclusive basis or not.

  On the other hand, the terms on which such rights are conferred should be determined, such as the time frame (lapse of time to use the rights) and the material range (for which activities the company may use the technology), as well as the possibility of assigning the technology or subleasing it.

- **Compensation**

  There is a wide range of ways to allocate compensation, which would depend on the following factors:

  – Time of accrual: payment upfront or deferred payment
  – Basis for calculation: current value, milestone performance, future sales, etc.
  – Methods of payment: in cash or in kind (e.g., participation in the company)

  Thus, there can be different, compatible ways of compensation (such as payment upfront or royalties), which may correspond to different factors.

  Likewise, the parties may agree to an initial grace period (no payment within a determined time frame), so that compensation can be adapted to the time line when profits are expected to be generated.

  As long as the compensation is of a variable character and is subject to certain milestones or indexes, research centres may retain monitoring and control measures of the exploitation (e.g., audit rights).

- **Rights on developments and technology improvements**

  The grant of the licence will not necessarily prevent the continuation of research on the technology, which may lead to new developments and improvements. Such improvements may also be generated by the company using the technology, mainly to suit it to its needs.

  It will therefore be desirable to regulate what the rights may be to the improvements and developments on the technology that can be developed by the parties. These rights may be, depending on the party that generates them, preferential rights to purchase (for the company) or licence to use for research purposes (for the research centre).

- **Provisions for the protection and defence of the technology**

  An essential element of the relationship will be the regulation of rights and obligations arising from the protection of the technology. This will imply the definition of the course of action to planned and on-going procedures, and also the claims or violations by third parties.

  In these clauses, it shall be defined which party will be responsible for applying for the intellectual property rights on the licenced technology, as well as the protocol to follow regarding defence actions. It would also be advisable to establish how the costs for such actions will be allocated.

- **Assumptions of liability and indemnity**

  In general, research centres, pursuant to the orientation of their researchers, do not tend to guarantee the full applicability of the technologies they have developed to the needs of the company, nor do they fully ensure that there are similar technologies on the market that have been developed in parallel to the relevant technology.

  Therefore, research centres limit the liability scenarios against third party claims regarding the ownership of the technology, problems arising out of its exploitation, or the inability to exploit the technology.

- **Protection of the public interest**

  Public research institutions, due to their nature, tend to reserve a number of powers in order to

protect the public interest and ensure adequate dissemination of the technology that they have created, and likewise to adapt to the legal framework applicable to them.

Therefore, technology transfer contracts with public entities tend to provide certain powers to accomplish those purposes. Among others, we can highlight the following:

– Licence for research: public research centres will secure the possibility to continue the scientific exploitation (not commercial) of the technology in question, which in the end will permit the centre to continue with research and, when applicable, the generation of improvements or new technologies.

– Right of reversion: the willingness of public authorities to ensure adequate dissemination of technology. Accordingly, the parties may agree that the contract shall be terminated and rights returned, in situations such as total or partial disuse of the technology, termination of activity by the company or the use of the technology for activities that are not in accordance with the guiding principles of the research centre.

Quick Guide for transfer of public research results to third parties

TRANSFER OF PUBLIC RESEARCH RESULTS TO THIRD PARTIES: AGREEMENTS THROUGH LICENCES

QUESTION 6. HOW TO NEGOTIATE A TECHNOLOGY TRANSFER AGREEMENT?

Key Issue: Identify the best procedure applicable to Technology Transfer

Technology Transfer: all those agreements, irrespective of their legal status, which allow a relevant individual to obtain rights over knowledge, works and inventions created by another.

- Transfer subject to private regulation: possibility of free negotiation between the two entities (direct award).
- Transfer subject to public regulation: possibilities depending on the applicable regulations.

Consider the procedure to be applied

- Competitive bidding
  - Advertising: public advertising, or limited to entities designated by the centre.
  - Submission of application.
  - Award based on criteria: economic conditions, technical requirements, other.
- No competitive bidding: free negotiation (transfer of technology agreement)
  - Non-Disclosure Agreement: use of information only for the assessment of the operation
  - Prior Negotiation (Letter of Intent): previous agreements reached and rules of negotiation (schedule, exclusivity, expenses, non-compliance).
  - Technology Audit: points to check: innovative character (if no patent right applied), features and functionalities
  - Negotiation
    - Interest for the company: fullest extent possible right to use and exploit with best economic conditions. Interest for the centre: maximum social dissemination, use for research, proper economic consideration.
    - Regulation: transfer of technology agreement.

Key Issue: Define the Transfer of Technology Agreement clauses

Transfer Technology Agreement: the document that will govern the grant of the rights by the centre to exploit the technology or the knowledge in the general market. The research centre of origin usually retains a series of powers to protect its interests in the exploitation of the technology.

Quick Guide for transfer of public research results to third parties *(CONT.)*

TRANSFER OF PUBLIC RESEARCH RESULTS TO THIRD PARTIES: AGREEMENTS THROUGH LICENCES

QUESTION 6. HOW TO NEGOTIATE A TECHNOLOGY TRANSFER AGREEMENT?

Terms and conditions of the transfer

- Kind of transfer: licence (usual, the centre maintains ownership but gives the company the rights to use and exploit) or transfer of full rights (the company becomes the sole owner and may freely relate the technology in their activities). Exclusivity or not.
- Time frame to use the rights.
- Material range (in which activities the company may use the technology).
- Possibility of assigning of subleasing.

Compensation

- Topics: time of accrual, basis for calculation, methods of payment.
- Ways of compensation: payment upfront, royalties.

Rights on future developments and technology improvements

- Developments from public centre: preferential rights to purchase.
- Developments from private company: licence to use for research purposes.

Provisions for the protection and defence of technology (regulation of rights and obligations arising from the protection of the technology)

- Who will be responsible for applying the provisions?
- Protocol regarding defence actions.
- Allocation of costs.

Assumptions of liability and indemnity: In general centres do not tend to guarantee the full applicability of the technologies to the needs of the company, nor they fully ensure the existence of similar technologies. Assumptions that may be regulated:

- Full applicability to the needs of the company.
- Existence of similar technologies on the market.
- Ownership of technology.
- Problems arising out of its exploitation.
- Inability to exploit the technology.

Protection of public interest: Public Research institutions tend to reserve a number of powers in order to protect public interest and ensure dissemination

- Licence for Research and generate improvements or new technologies.
- Right of reversion to ensure adequate dissemination in cases such as disuse, termination of the activity of the company or use not in accordance with the guiding principles of the research centre.

NOTE: Find the complete Quick Guide for Technology Transfer to Business in Chapter 4

E. CREATION OF A COMPANY AS A MECHANISM FOR TECHNOLOGY TRANSFER

Technology transfer to third parties is a mechanism by which the research institution takes a passive role in the exploitation of research results, because its activity is limited to functions of protection and control of its interests.

However, there are other possibilities in which the centre can get involved and develop a more active role, which preferably will be by means of the creation of a new entity to develop the commercialisation of the technology, where the centre will participate to a greater or lesser extent.

In the field of research, there is additionally a specific figure: the spin-off[10].

The Creation of a Spin-off

Researchers who developed the technology in a research centre promote the creation of a spin-off in order to handle the direct commercialisation of the technology. The creation of such a spin-off (from a research centre) is a policy that receives a great deal of support from the government as a mechanism to enhance their development and generate new business projects in the field of innovation.

In this regard, the European Commission has also been active on this issue:

> *"12. Develop and publicise a policy for the creation of spin-offs, allowing and encouraging the public research organisation's staff to engage in the creation of spin-offs where appropriate, and clarifying long-term relations between spin-offs and the public research organisation".*

The creation of a spin-off will be determined by two key points:

- **The possibility of participation of researchers in the project**

  The participation of researchers in the capital and the activity of a company is a possibility that is not always suited to the legal regulation of internal protocols and research centres.

  Likewise, the fact that researchers combine their activity in the centre with this new venture can lead to potential conflicts of interest between their activity in the centre of research and the economic interests arising from their participation in the company.

  To promote such activities, research institutions tend to develop internal protocols for the creation of companies by researchers, allowing them, within the existing legal framework, to manage their participation in the spin-off, and where appropriate, its compatibility with activities for the research institution.

[10] PRES- University of Toulouse: "According to French laws, spin-offs from universities aim at developing breakthrough technologies in emerging markets. Some will grow as SMEs, while others will be bought up by big companies once their business model is shown to be relevant. The spin-off followed by incubators and benefiting from law layout are more successful than others. Unlike in the US and in Germany, very few of them will grow to big SMEs (more than 2,000 employees)".

Research centres usually develop internal protocols to help researchers to manage the complexity of combining their research activity in the centre with the contribution to their new company (possible conflicts of interest).

- **Possible participation of the research institution**

  The creation of the company will require the transfer of rights of use and exploitation of the research results that are the object of their activity.

  As a mechanism of compensation for such a transfer, it may be agreed that the centre may participate in the capital of the company, either at an early stage or later on.

  Thus, the spin-off is not required at an initial stage to meet an economic return for the transfer of technology. On the other hand, the centre can link its remuneration to the economic development of the company, and accordingly have new ways to obtain compensation.

Regulation of relations between partners: the shareholders' agreement

In either of the scenarios above, the research centre's participation in a company created in order to exploit a technology developed within its organisation will require the regulation of the cohabitation of its partners.

In this regard, it should be taken into consideration that in these companies, partners with a very different profile (research centre, researchers, private investors, companies from that sector of the industry, etc.) can coexist, and with an individual very specific interest. Therefore, the prior negotiation of a Shareholders' Agreement in order to prevent potential future conflicts is highly recommended.

The Shareholders' Agreement will cover the main aspects of the company, its management and administration, and the partners' relationships.

Furthermore, each of the parties involved will tend to bear some powers to enable them to protect their interests. Thus, in the case of the research institution, in addition to their economic interests, they will seek to ensure the effective exploitation of the technology, and the possibility of leaving the company whenever appropriate in their interests.

On a general basis, a Shareholders' Agreement of a technological company will cover the following topics:

- **Transfer of shares regime**

  One of the essential elements in the relationship between the partners will be the description of the regime for the transfer of shares, as it will define the opportunities for partners to plan freely their divestiture in the company and participate in the sales opportunities that may arise.

  To this effect, various mechanisms for transfer of shares can be considered:

  – Pre-emptive rights: whenever a partner receives an offer from a third party to acquire its shares, the remaining partners or the company will have a pre-emptive right to acquire those shares in the same conditions.

  – Tag-along: if the preemptive rights are not triggered, the remaining partners will be allowed to participate in the sell in proportion to their participation in the capital.

  – Way out rights: one of the partners (in particular, the public centre) may reserve a right to leave the company when it deems it most appropriate. Then, the other partners or the company will acquire its stake following the economic conditions that are established in the Shareholders' Agreement.

    This mechanism may also occur in case of serious breach of contract that will force the centre to cease being a member of the company.

  – Better fortune clause: finally, in the case of the transfer of shares, the transferring partner may reserve a right that will be applicable whenever the acquiring new partner that acquired the shares, transfers such shares to a third party

on more favourable economic conditions than the ones that governed the first transfer.

In such a case, the transferring partner is entitled to receive a portion of the benefits obtained by the partner that transfers the shares on a second occasion, applying the percentage that they may have agreed upon in the Shareholders' Agreement.

The Shareholders' Agreement attempts to prevent future conflicts by regulating the particular interests of the different partners. Main aspects covered are: transfer of shares regime, management and administration of the company and conflict rules.

- **Management and administration of the company**

In addition to the transmission of shares, it will be essential to establish the rules for the management and administration of the company, which will cover mainly the following elements:

– Composition of the governing body: how members of the governing body will be elected. Generally, the election will be apportioned among members between the different partners, so that each of the existing profiles is represented in proportion to their participation.

Unlike other profiles with a greater involvement in the activity of the company, such as entrepreneurs and private investors, the research institution will not be required to be a member of the board; it may be sufficient with other mechanisms such as those listed below.

– Rules for the adoption of agreements: the partners may agree that a number of matters that have a strategic character may require a greater majority to be passed, above all to gather a major consensus in the decision. Likewise, it may also be envisaged that some decisions may be subject to a veto by a specific partner (e.g. those relating to technology from the research centre).

– Right to information and auditing: a system may also be established for monitoring the activity of the company, by means of which managers should keep the shareholders informed on a regular basis of the evolution of the activity of the company, both in financial matters as well as in other aspects (commercial, technological, etc).

This right may be accompanied by the possibility of requesting an audit of the accounts at the request of shareholders.

- **Conflict rules**

Rules of conflict contain the procedures to be followed in the case of breach by either party. Thus, the member who has failed to perform accordingly may be allowed time to remedy the situation or set the procedure for compensation for the damage caused.

To this effect, the Shareholders' Agreement may establish mechanisms for the party in breach to respond for the damages caused. Among several options for compensation, the compulsory sale of shares at a price below that of the market may be included.

Finally, the arbitration procedure to be followed whenever conflicts among partners arise in regards to the interpretation or implementation of the Shareholders' Agreement may also be covered in the Shareholders' Agreement.

Quick Guide for creation of a company as a mechanism for technology transfer

CREATION OF A COMPANY AS A MECHANISM FOR TECHNOLOGY TRANSFER

QUESTION 7. WHEN SHOULD A COMPANY BE CREATED?

Key Issue: Key points to consider the creation of a Spin-off

Technology Transfer: all those agreements, irrespective of their legal status, which allow a relevant individual to obtain rights over knowledge, works and inventions created by another.

- Transfer subject to private regulation: Possibility of free negotiation between the two entities (direct award).
- Transfer subject to public regulation: Possibilities depending on the applicable regulations.

Technology Transfer by creating a new entity is a mechanism by which the research institution gets involved in the exploitation of research results. This model is currently being highly encouraged from governments and universities.

Possibility for researcher to participate in the capital and the activity of the company: Legal regulation and internal protocols. Need to prevent conflicts of interest.

Possible participation of research centre: Participation as a mechanism of compensation for technology transfer. Regulation of relations: Shareholders' Agreement

Key Issue: Dealing with partners having different profiles and interests, the Shareholders' Agreement

Transfer of shares regime: description of the regime that will regulate the mechanisms for transfer of shares, and define opportunities to plan divesture and /or participation in the sales opportunities:

- Pre-emptive rights from co-partners if there is an offer from a third party.
- Tag-along: all co-partners are allowed to participate in the sell in proportion to ownership
- Way out rights: if a co-partner wants to leave the company, the other partners may buy the shares under pre-defined economic conditions
- Better fortune clause: if an acquirer sells transferred actions at higher price, the transferring partner is entitled to receive a pre-defined portion of the benefits.

Management and administration of the company

- Composition of governing body (research institutions not required to be members of the board)
- Rules for the adoption of agreements (major consensus, right of veto...)
- Right to information and auditing (system for monitoring the activity of the company)

Rules of conflict: procedures to follow in case of breach by either party

- Ways to compensate (e.g., compulsory sale of shares at a price below market)
- Arbitration if conflict in regards to interpretation or implementation of the Shareholders Agreement.

NOTE: Find the complete Quick Guide for Technology Transfer to Business in Chapter 4

3. THE PROCESS FOR IDENTIFYING TECHNOLOGY WITH POTENTIAL: THE MOST IMPORTANT SOURCES AVAILABLE

A complementary phase of the procedure of transfer of technology developed in this guide is the ability of Technology Transfer units to communicate to the business community the grant of the patent. This phase will be necessary in those cases where the results have been developed independently by the research centre, without collaboration or without being commissioned by the private sector, and after the specialised units have evaluated and protected these results.

This section will focus on how the news of a patent is communicated to the business community. Tools and channels that allow the identification of technology suitable to be applied to the business environment are then presented (patent rights, inventions, know-how). The aim is to provide biotech companies with elements that facilitate the identification of technologies with market potential, such technology being from public research environments (universities, research institutes, technological institutes and centres, etc). Sources through which biotech companies may find these technologies are listed below:

- Offices for technology transfer
- Research institutes
- Technology brokers
- Internet sites
- Databases
- Social media
- Tools of the European Commission
- Journals
- Exhibitions, specialised meetings, brokerage events
- Software

One can note that these sources are quite varied: offices, institutions, companies, software tools, publications, meetings, etc. But broadly speaking, on a straightforward approach, there are two major sources:

- Those that are single research institutions (or a few at most)
- Those that are an aggregation of multiple institutions

Regarding the latter, the public environment and the market – though mainly the market – have developed mechanisms to aggregate all the information given by individual providers. These aggregators are private companies (technology brokers), databases, magazines, websites, etc.

Offices for Technology Transfer

All research universities have their respective technology transfer offices. Their names may differ: Technology Licensing Office, Technology Transfer Office, Licensing Office, Office of Intellectual Property and so on. All these technology transfer offices develop websites to offer technology that is available for licensing.

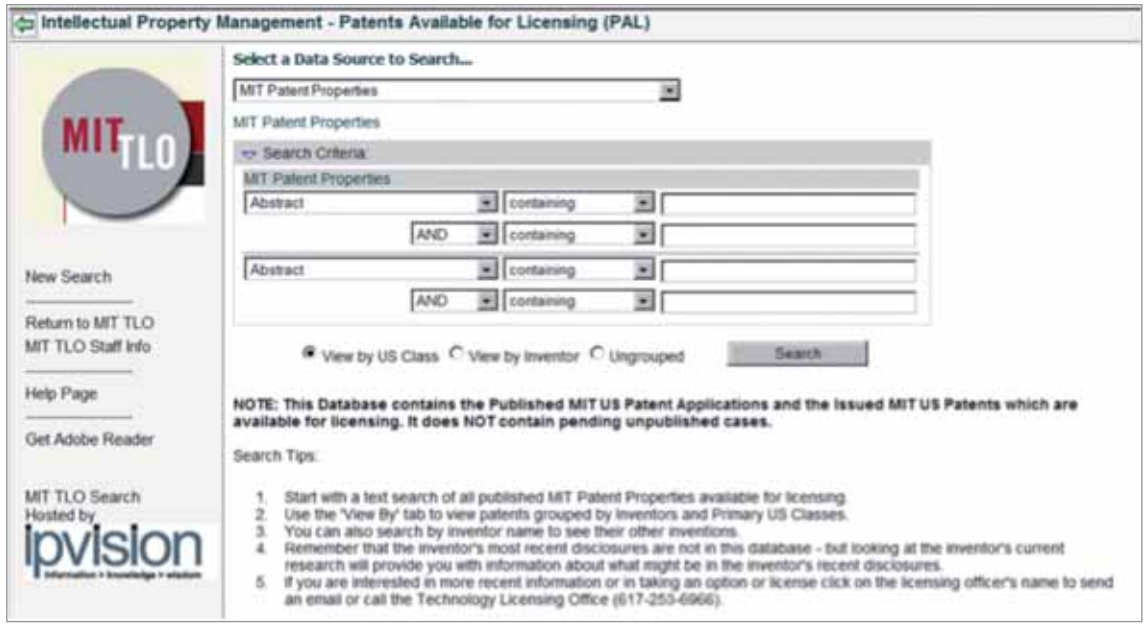
Figure 15: Examples of technology transfer offices

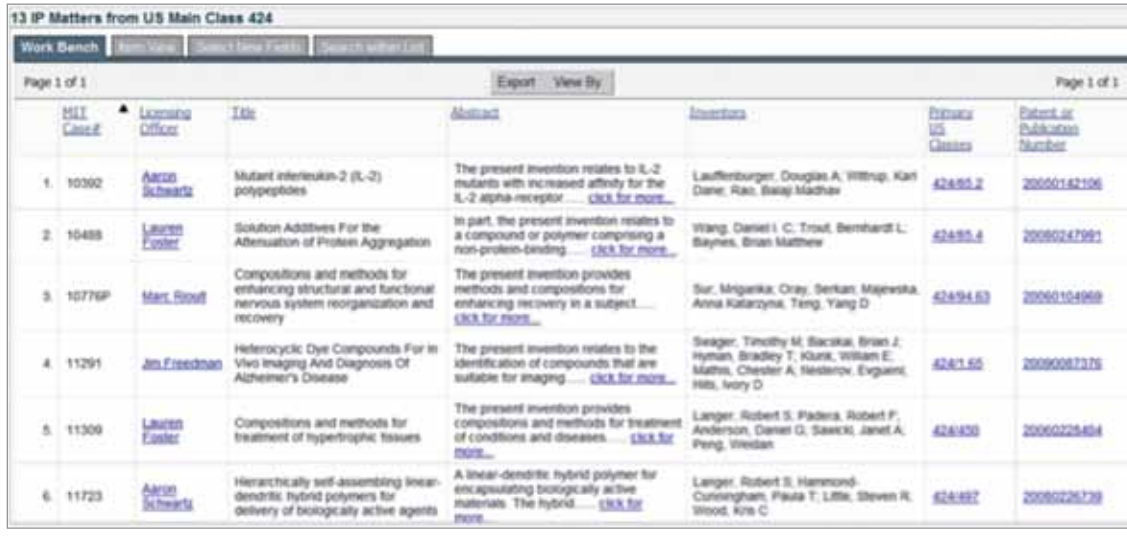
UNIVERSITY	TECHNOLOGY TRANSFER OFFICE
• Columbia University	• Columbia Technology Ventures (S&TV)
• Consejo Superior de Investigaciones Científicas	• Oficina De Transferencia de Tecnología
• Group of Universities of the Area of North-Rhine/ Westphalia	• Provendis
• Higher Education Institutions in Baden-Württemberg	• Technology Licensing Bureau (TLB)
• Imperial College of Science, Technology & Medicine	• Imperial Innovations, Ltd
• Katholieke Universiteit Leuven	• Leuven Research & Development
• Massachusetts Institute of Technology (Mit)	• Technology Licensing Office (TLO)
• Michigan State University	• MSU Technologies
• Penn State University	• Tech Transfer - Intellectual Property Office
• Public Universities in Washington State	• Washington Research Foundation (WRF)
• Simon Fraser University	• Innovation Office (IO)
• Stanford University	• Office of Technology Licensing (OTL)
• Technion Israel Institute of Technology	• Dimotech Ltd
• Toulouse University	• Toulouse Tech Transfer
• Universitat Autònoma de Barcelona (UAB)	• Centre de Transferència de Tecnologia (CTT)
• Universitat de Barcelona (UB)	• Fundació Bosch i Gimpera (FBG)
• Universitat de Girona (UdG)	• Oficina d'Investigació i Transferència Tecnològica i de Coneixement (OITT)
• Universitat de Lleida	• Oficina de Suport a la R+D+I (ORDI)
• Universitat Politècnica de Catalunya (UPC)	• Centre de Transferència de Tecnologia (CTT)
• Universitat Politècnica de València	• Centre de Transferència de Tecnologia (CTT)
• Universitat Pompeu Fabra (UPF)	• Servei de Recerca i Unitat d'Innovació i Parcs
• Université de Bordeaux	• Aquitaine Valo - service de valorisation
• Université de Genève (*)	• Unitec
• Universities of Zurich and Berne (*)	• UNITECTRA
• University of Alberta	• TEC Edmonton
• University of Calgary and Other Universities	• University Technologies International Inc.
• University of California	• Office of Technology Transfer (OTT)
• University of California - Berkeley	• Office of Technology Licensing (OTL)
• University of California - Los Angeles (Ucla)	• Office of Intellectual Property Administration
• University of Harvard	• Office of Technology Development (OTD)
• University of Manchester	• UM Intellectual Property Limited (MIP)
• University of Michigan	• UM Tech Transfer
• University of New Mexico (UNM)	• Science & Technology Corporation (STC)
• University of Oxford	• Isis Innovation Ltd
• University of Sheffield	• Fusion IP
• University of Warwick	• Warwick Ventures
• University of Washington	• UW Center 4 Commercialization (UWC4C)
• University of Wisconsin - Madison	• Wisconsin Alumni Research Foundation
• Virginia Polytechnic Institute and State University	• Virginia Tech Intellectual Properties, Inc

(*)Swiss universities provide the information referring to technologies available for licensing licensing through the system swiTT, the Swiss Technology Transfer Association.

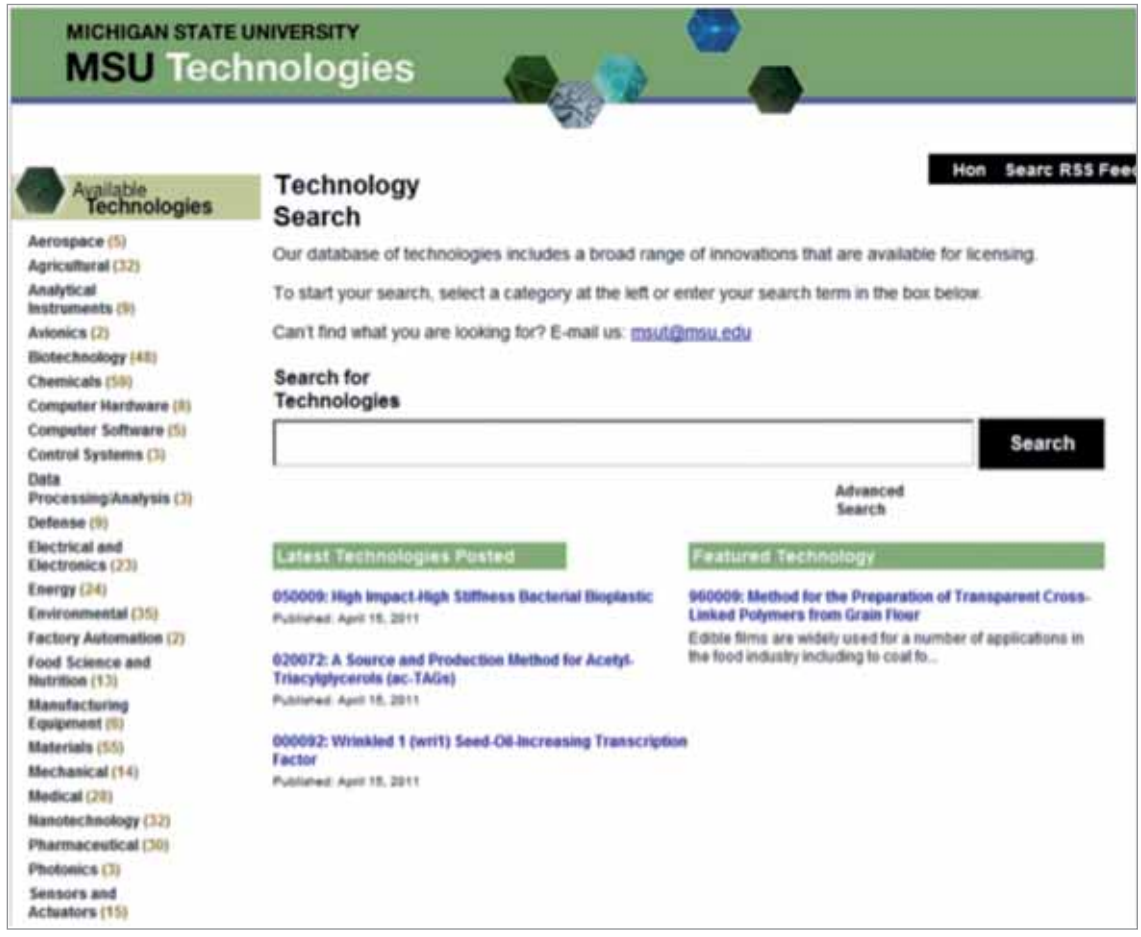
The following are some examples of information that can be found on the websites of these offices of technology transfer:

› **Example 1:** Technology Licensing Office (TLO) at MIT offers a query system across its whole portfolio of inventions.





- **Example 2:** A second example is from Michigan State University:



- **Example 3:** Finally, an example from Universitat Politècnica de València, with its CARTA (catalogue of available technologies):

How are these technology transfer offices found? University websites facilitate the identification of these commercial structures within their academic organisation. By identifying the research university, one can rapidly find the office of technology transfer where the offers of available technologies are published. Research university websites can be found directly by name or through academic associations, some of which include:

- Association of American Universities
- Association of American Colleges and Universities
- European University Association (EUA)
- Universia
- International Association of Universities

The ministries of education and research of individual countries may also be a useful source for identifying relevant universities. For example, in France, the Ministère de l'Enseignement supérieur et de la Recherche provides a list of all the universities in the country on its website.

Associations of technology transfer offices also facilitate the identification of individual units of commercialisation. The most important international groupings include:

- Association of University Technology Managers (AUTM)
- Association for University Research and Industry Links (AURIL)
- Licensing Executives Society International (LESI Inc.)
- Association of European Science and Technology Transfer Professionals (ASTP)
- Technology Innovation International (TII)
- Proton Europe, the European Knowledge Transfer Association
- European Association of Research and Technology Organizations (EARTO)
- European Association of Research Managers and Administrators (EARMA)

Nevertheless, all countries and certain regions have their own particular association. For example:

- Spain: Red Española de Oficinas de Transferencia de Resultados de Investigación (RedOTRI)
- France: Réseau C.U.R.I.E, which provides the France Transfert Technologies service for any partner, especially companies.
- Switzerland: University Companies Association (UNICO), swiTT. In this case, swiTT provides access to a database of technologies available to all universities that belong to the association.

Research Institutes

Universities, engaged in teaching and research, are not the only institutions that create knowledge. The great majority of countries have large research institutions that are not engaged in academic research. Moreover, there are institutions with a technological profile that boast a more practical approach. Although these institutions as a whole may lack the uniformity that exists among universities, the general features are the same in every country. A few examples of such institutions are:

- Battelle Memorial Institute, an entity with a private profile that has a workforce of 22,000 people distributed in 130 locations around the world
- Stanford Research Institute, with 2100 employees
- Hundreds of laboratories and research institutes sponsored by various government de-

partments and agencies of that country. For instance, the United States Department of Energy National Laboratories sponsored by the Department of Energy (DOE) and the National Institutes of Health.
- Fraunhofer Gesellschaft, with 60 institutes spread throughout Germany that employs over 18,000 people
- Consejo Superior de Investigaciones Científicas - CSIC, with 12,000 employees
- Centre National de la Recherche Scientifique - CNRS, a workforce of some 34,000 people
- Max Planck Society, with about 14,000 researchers
- Technology centres in Spain, grouped within the Federación Española de Organismos de Innovación y Tecnología (FEDIT, Spanish Federation of Innovation & Technology Organisms), which has more than 50 centres as partners and a work force of nearly 8,000 people

Similar to the websites of universities, the websites of these institutions provide details of inventions available for licensing. They are, therefore, a highly relevant source for biotech companies looking for innovations ready to be marketed.

Lastly, many of these websites offer subscriptions to newsletters that report on research and technological opportunities available at their respective institutions.

Technology Brokers

All research institutions mentioned in the two sections above provide individualised information. Each and every one presents its inventions to the public. However, specific sites and institutions that specialise in aggregating information from several production institutions have been founded to facilitate the task of identifying technologies. The private business sector has been particularly active in this respect (see figure 16).

Figure 16: Companies providing aggregated data on technological opportunities

- Advanced Technology Innovations, Inc. - Created in 1985, the company seeks technologies commissioned by big corporations. Its clients include over 80 Fortune 500 companies. To find solutions, they approach small businesses, universities, technical consultants, private research organisations, etc.
- Amritt, Inc. - Global Innovation Practice, it provides various services related to relations between the West and China and India. One of these services is a system of technology scouting, oriented to identify technology in those two countries on behalf of Western companies
- Angle Technology Group
- British Technology Group (BTG)
- Competitive Technologies, Inc.
- Elyior
- Flexx Innovation - They define themselves as experts in technology scouting. This is currently their only activity.
- General Patent Corporation - offers a brokerage service for patents, although it is not the central part of its activity.
- Global Technology Transfer Group
- H2O Venture Partners - This is a company that invests and develops emerging technologies identified in the public sector. It is therefore a broker-investor. It is a model that is similar to the one adopted by Janus. However, they offer a specific service for technology scouting.
- High Spin Licensing
- Iceberg Transactions

- Idea Broker
- IdeaConnection
- Inflexion Point
- Innova S.p.A.
- Innovaro - (formerly UTEK Corporation)
- Innovation Center Denmark - They offer a scouting service to Silicon Valley companies that want to enter the sector. They help identify potential partners and technologies at a local level.
- Innovation Spectrum
- Inventors Workshop International Education Foundation (IWI) - is an entity that was created in 1971 to support not only creators of technology but also companies seeking new inventions.
- IP Pragmatics
- IP SOLUTIONS™ - a consulting reference in Portugal, specialising in issues related to intellectual property and technology transfer.
- IP Tactics
- iP2BIZ - through their program IPscore, they identify technologies, assess them and validate their market potential.
- IPG - Intellectual Property Group
- IPMetrics LLC - devoted primarily to the economic part of intellectual property transactions (monetisation, valuation, costs of violations, etc.).
- Licensing Technology Network (LTN)
- Nerac, Inc
- NG Group - their scouting service offers a window on technology developed in the state of Israel.
- NineSigma
- Ocean Tomo - they act as technological brokers through their premier interdealer broker service, ICAP Ocean Tomo.
- Orion Capital Group - offering various services in the field of technology, including the brokering of technology.
- Perception Partners®
- Pluritas LLC - helps clients find companies interested in buying their technology. They are primarily targeted toward large companies.
- Quaestio GP -supports companies in the health sector, pharmaceuticals, medical devices, functional foods, cosmetics, etc. to identify and acquire technological opportunities.
- Research Corporation Technologies (RCT)
- SkyQuest Technology Consulting Pvt. Ltd
- Techtran Group
- Tynax - is located in Silicon Valley and has an online system of buying and selling technology. It has more than 150,000 patents and technologies to sell. The company combines the service with advice on the transfer process.
- Via Licensing
- Zernike Group

Internet Sites

Many of the above-mentioned companies have Internet tools that facilitate research. In fact, the Interbio project provides a brokerage platform. However, there are business proposals for which the input is focused entirely on providing a platform for intermediation. (See figure 17).

Figure 17: Internet sites focused on providing an intermediation platform

- YET2 (www.yet2.com) is one of the strongest sites. Created in 1999, YET2 puts together buyers and sellers of technology.
- Innoget (www.innoget.com)
- inpama.com (www.inpama.com)
- The Technology Forum (www.technology-forum.com) is a site that is promoted by the European Space Agency (ESA).
- Patent Auction.com (www.patentauction.com)
- Idea Trade Network (ITN) (www.newideatrade.com)

Other miscellaneous platforms include:

- IP Marketplace (www.ip-marketplace.org) - Danish Patent and Trademark Office

Figure 17: Internet sites focused on providing an intermediation platform *(CONT.)*

- Conectus Alsace (www.conectus.fr)
- www.biomedical-outsourcing.com - outsourcing site for the biopharmaceutical sector. It includes information from several countries. Provides opportunities generated at 150 institutions.
- www.agrifoodbiz.com - like the previous site, this site is dedicated to the sector of agrobiotechnology.
- www.biodevicesbiz.com - for the sector of medical devices
- www.inventionbuy.com

Databases

Knowledge Express (www.knowledgeexpress.com) provides a useful information system for technology transfer, intellectual property, licensing and marketing. The service is a collection of almost 30 data bases on transfer agreements, company profiles, clinical analysis, agreements, drug pipelines, drug sales, patents, royalties, etc. (See figure 18).

Figure 18: List of databases included in knowledge express website

- TechEx - Provides information about technological opportunities in life sciences. Includes abstracts of technologies ready to be licenced, obtained directly from universities or research institutes. The database is updated daily.
- UVentures - It is similar to TechEx (above) but in the field of physical sciences. Together with TechEx, they manage 50,000 UVentures and technologies.
- KE Agreements - Provides information about the contents of licence agreements and technology transfers.
- KE Biomedical Deals - Database transfer agreements in the biomedical sector.
- BioScan: Database of over two-thousand biotech companies around the world.
- KE Device Pipeline - Database of medical devices in 35 areas of medicine from thousands of companies. The information comes from hundreds of sources globally.
- KE Drug Pipelines - Database of drugs in various stages of development, thousands of companies that target hundreds of diseases.
- Biomedical Industry Analyzer - Information on biotech companies, pharmaceuticals, diagnostics, medical devices, bioinformatics, etc.
- Biomedical NewsSearcher - File of press releases from biotech companies reporting clinical analysis, patents, agreements, mergers, changes in management teams, etc..
- Federal Research In Progress (FEDRIP) - Information on research projects funded by the US federal government.

Social Media

Most of the offices of technology transfer and technology brokers are present on Facebook, LinkedIn and Twitter. From these social networks, they direct any user to their respective websites. Information is also available on YouTube.

Many companies and technology transfer units have also linked their websites to a relevant blog, with daily updates, always related to research and technology. Some technology transfer offices update their information via RSS (Really Simple Syndication). This is a tool that, despite its existence before the emergence of the social media concept, has been strengthened by mobile technologies and the wide use of blogs.

Tools of the European Commission

- Enterprise Europe Network. This network puts together nearly 600 business support organisations from 47 countries. The network has several databases, and furthermore, the contact points in each country facilitate interaction in each region.
- Technology-market.eu (www.technologymarket.eu). One of its tools is a database that provides information technology opportunities, which offers 12,000 technology profiles. It is updated every week. One can receive information through e-mail and can integrate this information to the websites of the organisations concerned.
- Joint Research Centre (JRC). Provides information about 50 new technological opportunities on a weekly basis.

Journals

- **CORDIS - research * eu**: The research * eu supplement presents the most outstanding technological offers and news of projects within the European research and development sector. It is published in English ten times a year and provides updates on research funded by European funds, emphasizing exploitable technologies and lists to be marketed that they have created. They cover topics, ranging from biology to medicine, or energy and environment to IT, telecommunications and industrial processes. In March 2011, the supplement of results of research * eu was renamed journal of results of research * eu, especially to reflect its key role in the publications of research * eu.
- **JRC newsletter.**

Brokerage Events

There are many events related to biotechnology. Business associations, regional and state agencies for innovation and the agents responsible for the clustering of biotechnology reports on the subject in great detail. Some examples are listed below:

- BIO International Convention, from the Biotechnology Industry Organization
- Global Bio-business Forum, BioAsia
- Biobusiness
- BIOTECHNICA
- Biospain

In these meetings, companies are able to identify technology partners and technologies suitable for licensing.

Software

Rather than identify opportunities, software solutions are aimed at evaluating technologies, technological surveillance or to a well-known area for the company, competitive intelligence (with software such as Knowledge Works Wincite). Below are a few references of software specialised in surveillance and assessment technology.

Vigiale de IALE, surveillance technology platform

IPscore ® is software designed for any company that has patent- and conduct-technology development projects. This software allows prioritising patents or development projects based on their potential and commercial value. Likewise, it builds a model that facilitates the evaluation of patents. The program is useful for obtaining a point of reference for the value of a given technology.

PatentRatings is software for statistical analysis and ratings of patents. It is targeted to businesses, investors and patent attorneys. PatentRatings has developed a very sophisticated system for rating patents. They call it the Intellectual Property Quotient or "IPQ". It is based on a statistical methodology. The service is useful for evaluating patent portfolios and for identifying those patents with a higher likelihood of economic success.

The company **Consor** has a range of products aimed at the evaluation of technologies. For example, the technique VALMATRIX analyses 20 different features associated with intellectual property that strive to assess, together with the owner of the technology, its potential use. These features cover several aspects such as finance, legal strength, marketing activities, competition, etc.

4. QUICK GUIDE FOR TECHNOLOGY TRANSFER TO BUSINESSES

This Quick Guide pretends provide you with a summarized view of the contents of the white paper "From research to market: key issues of Technology Transfer from public research centres to business".
It provides short and concrete answers for seven main questions, all of them complemented with further explanations and examples available in the main body of the white paper.
The seven questions answered are:

- Question 1. How to allocate ownership of new creations?
- Question 2. Is it possible to incentivise involved researchers?
- Question 3. Is the Technology protectable?
- Question 4. Has the technology been patented?
- Question 5. Is the technology worth?
- Question 6. How to negotiate a Technology Transfer agreement?
- Question 7. When should a company be created?

REGULATION OF RESEARCH IN PUBLIC CENTRES: GOOD PRACTICES. *See pages (13-17)*

QUESTION 1. ATTRIBUTION OF OWNERSHIP?

Key Issue: Assess the scope of employee activity in the research centre

- Ownership and exploitation rights to the employer (Bayh-Dole Act, USA).
- Eligibility for protection of results: specific procedures.

Key Issue: Ensure prior agreements in collaborative research activities

- Description of the research project.
- Clarification of contributions: activity of researchers, rights to use existent knowledge and technology, funding and milestones.
- Outline of monitoring and control mechanisms of the project.
- Subcontracting or collaborating? Definition of rights over the project results and pre-existing technology, attribution of ownership and commercialisation rights.

QUESTION 2. PARTICIPATION OF RESEARCHERS?

Key Issue: Consider the compensation and remuneration of researchers

- Recognition of moral rights for the authors (EU Commission).
- Internal regulations of the centre to compensate researchers, especially when discovery exceeds contractual relationship.
- Mechanisms: Passive incentive (fair price, share in the benefits of the centre for exploitation), active participation of researcher (creation of company).

EVALUATION OF THE TECHNOLOGY
See pages (17-30)

QUESTION 3. IS THE TECHNOLOGY PROTECTABLE?

Key Issue: Evaluate the protection strategy

Protection strategy: should respond to the relevancy of business model to exploit the technology.

- Protection in biotechnology usually done through patents (monopoly right granted by the state over a technology for a limited time and a specific geographic area).
- Other protecting tools: utility model, copyright, trademarks, industrial secrecy, confidentiality rights,...
- When resources are limited, protection decisions should be aligned with research strategy.
- Initial 30 months have low cost, thus public research bodies increasingly initiate the drafting of the patent.

  Advantages: it demonstrates growing commitment to the social return on public research and greater ability to acquire public technology

  Disadvantage: despite technology transfer offices efforts, still low quality of patents, based on insufficient data and lack of previous studies of patent right

Key elements assessed in a patent:

- Date of priority (first in filing).
- Novelty: must not be qualified as a pre-existing knowledge accessible to the general public.
- Inventiveness: offer innovations not obvious to an expert in the field.
- Industrial application (not merely theoretical).
- Reproducible at any given moment.

QUESTION 4. HAS THE TECHNOLOGY BEEN PATENTED?

Key Issue: Technology patented – Verify:

The patent duly includes the technological development author's name. This point is especially relevant with respect to patents in the U.S.

The patent provides sufficient protection for the acquired technology and ensures solid holding.

The information has been treated confidentially.

If the patent has been granted in any country, confirm that the fees have been duly paid.

Key Issue: Patent in process – verify:

Priority Date (given with the filing of any king of patent: national, European or PCT).

Protection strategy matches buyer's interest - corrective actions for patenting process may be done by the buyer depending on the stage of the process.

- The strategy of abandoning National / European patent in favour of PCT permits the delay of payment of patents extensions but slowly reduce exclusive exploitation time).
- A patent can be enriched until publication with new claims and embodiments to improve the scope of protection and increase the chances to be granted.

Ensure availability of **preliminary reports on patentability** to anticipate problems in the evolution of the patent (or emulate them in collaboration with an expert) and a report on ***Freedom to Operate*** (identify potential constraints for commercial exploitation).

EVALUATION OF THE TECHNOLOGY
See pages (17-30)

QUESTION 4. HAS THE TECHNOLOGY BEEN PATENTED? *(CONT.)*

Key Issue: NOT PATENTED– Analyse and protect:

Evaluate the convenience of patenting the technology (necessary to have an expert in protection of intellectual property involved):

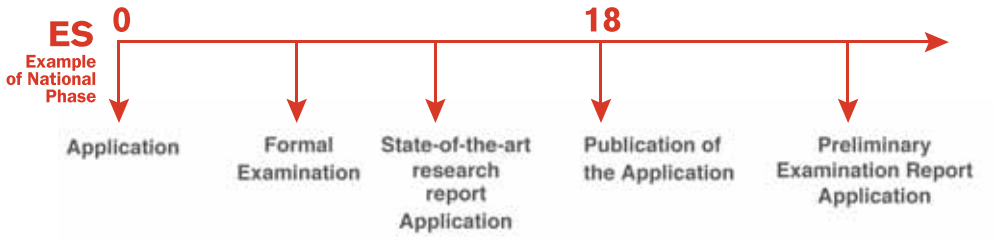
- Not worth protecting or the technology cannot be protected: opt for collaborative agreements with the research group.
- Interesting and likewise to protect the technology: ownership will remain with public centre, which starts the patenting process with the active involvement of the buyer.
  - Technology to be acquired can be improved and recovered economically.
  - Technology to be acquired can be protected, ensuring proper exploitation.

If the technology shall be protected

- Analyse the patent: Patent literature search through websites (www.espacenet.com) / (www.uspto.gov) and scientific publications, especially those published by the Centre.
- Confirm that data and results used in investigation were not in any way made available to the public (Any publication before the patent can mean an end to the novelty required for a patent).
- Verify that the processes of research carried out in relation to technology have been documented accurately, using standards approved by the respective patent offices.
- Request for *Patentability Report* (private report by independent expert) and Plan for the Strategy of Protection of technology through experts. Important: These experts will not have access to patents that have not yet been published.
- Report of *Freedom to Operate* (identify potential constraints for commercial exploitation).
- Analyse the right time to introduce the patent (the strength of a patent depends on the data and information included in the application).

Key Issue: Choose the most adequate patenting process

National Patent.



Advantages: reduced cost of fees in the initial stages (waived for public research institutions); often used by research centres. Provides Priority Date.

Disadvantages: it is necessary to replicate the process country by country.

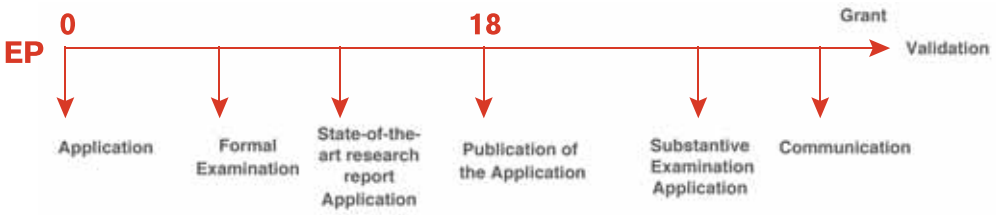
Documents to be analysed:

- Text of the patent
- Freedom to Operate (experts)
- Previous reports on patentability (experts)
- Reports of the Examiner (national office)

EVALUATION OF THE TECHNOLOGY
See pages (17-30)

QUESTION 4. HAS THE TECHNOLOGY BEEN PATENTED? *(CONT.)*

European Patent (about 20 countries)



Advantages: single request for Unified European offices. Provides Priority Date.

Disadvantages: payment of fees.

Documents to be analysed:

- Text of the patent
- Freedom to Operate (experts)
- Previous reports on patentability (experts)
- European Search Report (EESR): private non-binding preliminary report.
- Availability of European Search Report published by the European Patent Office (private report, at 6 months from the application submission)

Centralised procedure: PCT (Patent Cooperation Treaty, unified system for processing initial phases of request in about 100 countries)

Advantages: unified international process

Disadvantages: payment of fees

Documents to be analysed:

- Text of the patent
- Freedom to Operate (experts)
- Previous reports on patentability (experts)
- Possibility to request International Preliminary Examination (IPE)
- Availability of International Search Report (ISR) published by the International Bureau (WIPO) (public report 18 months after submitting the PCT application)

National extensions

- Evaluation of each country; payment of fees by country; part of the process is more expensive.
- Documents to be analysed: Objection by third parties

ASSESSMENT AND RECOVERY OF TECHNOLOGY
See pages (31-50)

QUESTION 5. IS THE TECHNOLOGY WORTH?

Key Issue: Understand the difference between three closely related terms

Assessment: assign a value to a product or technology. The assessment of a technology is basically the assessment of its patents and it's foreseeable capacity to generate future incomes

- Incorporating economic criteria for its evaluation: development of a technology is associated with negative (resources needed) and positive (income from exploitation) cash flows.
- Taking into account technological risk through discount risk rates or decision-making patterns (e.g. milestones and continuous assessment)

Recovery: perform the tasks necessary to increase the value of the technology in a given period of time, in order to promote technology transfer and ultimately, increase the value of the transaction. In early stages may involve simply improving IP strategy, in later stages choosing an application for the technology.

Maturity: covering all phases of a project to place it on the market. Recovery involves specific strategies focused in the transactions, inside the maturity.

Key Issue: Assessment - Choose the method to assess its value and maximize recovery (listed according to degree of complexity. Illustrative example based on pharmaceutical industry in corresponding Chapter 2C)

Methods based on the cost of the patent: the licensing of a technology leads to the recovery of the costs and investments undertaken by the licencee in the development of technology. Scarcely used except in urgent operations or calculation of initial down payment.

Advantages: Minimum cost of transaction for the promoter. The investment cost is usually used as a minimum purchase price sale.

Disadvantages: The seller does not consider the future value that technology can reach, which also means part of the future flows. The buyer does not have to admit that the technology has been developed properly.

Assessment system based on income and future costs: assigning a value to the current negative and positive economic flows associated with development and exploitation of technology

- Analyse and build scenarios based on
  - **the market** to be entered (size, competitors, entrance barriers and business model accepted),
  - **the future product** (expected gross margin and market penetration, its life cycle and product obsolescence) ,
  - **the acquired company** (potential ability / willingness to bring the product to the market/licence it).

Advantages:

- The seller participates in the future profits of exploitation.
- The buyer can determine the ROI (Return on Investment for acquiring the technology) in comparison to alternative investments.

Disadvantages:

- Assessment based on assumptions that if proven to be false will create instability and unreliability.

Complications:

- Determine discounting the values of future cash flows to establish the actual value (Net Present value, NPV).

ASSESSMENT AND RECOVERY OF TECHNOLOGY
See pages (31-50)

QUESTION 5. IS THE TECHNOLOGY WORTH? *(CONT.)*

Rating system based on tree of possibilities: Incorporate decision-making patterns that allow the evaluation of several scenarios. The successful completion of any of the stages involves a revaluation of the technology (recovery).

- Complete evaluation mechanisms for discounted cash flow through a tree of possibilities, when the probability of success of the different phases in a project being developed are known and can anticipate statistically options of success or failure of each milestone.
- Allows more flexible planning
- May evolve to more complex models: evaluation by real options.

  Advantages: Allows the assessment process associated with the contract transaction, involving future payments in the evolution of the value of the company. (See section "Negotiation of the Valuation")

Key Issue: Negotiate the valuation of the technology

Negotiation of the valuation: negotiation process where the buyer and the seller defend the hypotheses to reach the most satisfactory price or what would be considered a fair transaction.

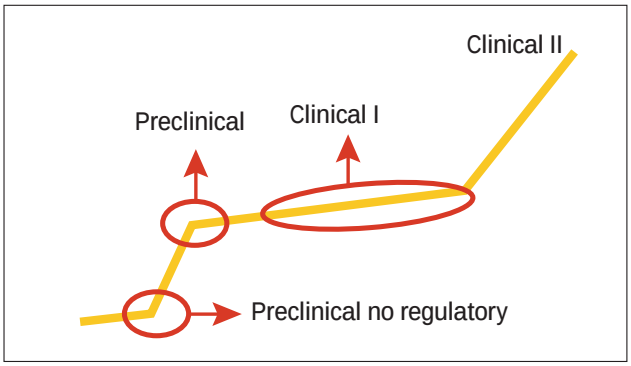
The purchase price of a licence in early stages of a product development, where the risk of failure is very high, is usually linked to payments associated to the achievement of goals (milestones), and these, to an increase of value of the product

A royalty may also be agreed, and calculated based on the percentage fee of the sales which the buyer pays de seller.

The seller uses the same discount rate as the buyer and the same tree of possibilities to calculate the NPV. Therefore, if the project is successful, the seller will enjoy a higher rate of return compared to that if the transaction had been made on a single payment.

Key Issue: Recovery - increase the value of the technology

Recovery in early stages: "package" technology in early stages to multiply the possibilities of and increase the transaction price



QUESTION 5. IS THE TECHNOLOGY WORTH? *(CONT.)*

- **Packaging:** enhance value by providing technologically specific actions, cheap and fast. Complete the assessment with the divestment strategies, evaluating whether it is possible to transfer it or sell it quickly or if the recovery requires a long-term plan.
- **IP Driving Research** (research aims), conducting experiments that sustain one by one the claims that construct the patent. Acquire technology with a defined regulatory package, the design of experiments necessary to improve the level of protection and demonstrate effectiveness.
- Targeting the right technology to the market, and a specific product.
- Strategy for the protection of intellectual property.
- Develop a production plan that takes into account concepts such as productivity and scalability.

TRANSFER OF PUBLIC RESEARCH RESULTS TO THIRD PARTIES: AGREEMENTS THROUGH LICENCES. *See pages* (50-56)

QUESTION 6. HOW TO NEGOTIATE A TECHNOLOGY TRANSFER AGREEMENT?

Key Issue: Identify the best procedure applicable to Technology Transfer

Technology Transfer: all those agreements, irrespective of their legal status, which allow a relevant individual to obtain rights over knowledge, works and inventions created by another.

- Transfer subject to private regulation: Possibility of free negotiation between the two entities (direct award).
- Transfer subject to public regulation: Possibilities depending on the applicable regulations.

Consider the procedure to be applied

- Competitive bidding
  - Advertising: Public advertising, or limited to entities designated by the centre
  - Submission of application
  - Award based on criteria: economic conditions, technical requirements, other
- No competitive bidding: free negotiation (transfer of technology agreement)
  - Non-Disclosure Agreement: Use of information only for the assessment of the operation.
  - Prior Negotiation (Letter of Intent): Previous agreements reached and rules of negotiation (schedule, exclusivity, expenses, non-compliance).
  - Technology Audit: Points to check: innovative character (if no patent right applied), features and functionalities.
  - Negotiation
    - Interest for the company: fullest extent possible right to use and exploit with best economic conditions.
    - Interest for the centre: maximum social dissemination, use for research, proper economic consideration.
    - Regulation: transfer of technology agreement.

Key Issue: Define the Transfer of Technology Agreement clauses

Transfer Technology Agreement: the document that will govern the grant of the rights by the centre to exploit the technology or the knowledge in the general market. The Research Centre of origin usually retains a series of powers to protect its interests in the exploitation of the technology.

Terms and conditions of the transfer

- Kind of transfer: licence (usual, the centre maintains ownership but gives the company the rights to use and exploit) or transfer of full rights (the company becomes the sole owner and may freely relate the technology in their activities). Exclusivity or not.
- Time frame to use the rights.
- Material range (in which activities the company may use the technology).
- Possibility of assigning of subleasing.

Compensation

- Topics: time of accrual, basis for calculation, methods of payment.
- Ways of compensation: payment upfront, royalties.

Rights on future developments and technology improvements

- Developments from public centre: preferential rights to purchase
- Developments from private company: licence to use for research purposes

TRANSFER OF PUBLIC RESEARCH RESULTS TO THIRD PARTIES: AGREEMENTS THROUGH LICENCES. *See pages* (50-56)

QUESTION 6. HOW TO NEGOTIATE A TECHNOLOGY TRANSFER AGREEMENT?

Provisions for the protection and defence of technology (regulation of rights and obligations arising from the protection of the technology)

- Who will be responsible for applying the provisions?
- Protocol regarding defence actions
- Allocation of costs

Assumptions of liability and indemnity: In general centres do not tend to guarantee the full applicability of the technologies to the needs of the company, nor they fully ensure the existence of similar technologies. Assumptions that may be regulated:

- Full applicability to the needs of the company
- Existence of similar technologies on the market
- Ownership of technology
- Problems arising out of its exploitation
- Inability to exploit the technology

Protection of public interest: Public Research institutions tend to reserve a number of powers in order to protect public interest and ensure dissemination

- Licence for Research and generate improvements or new technologies
- Right of reversion to ensure adequate dissemination in cases such as disuse, termination of the activity of the company or use not in accordance with the guiding principles of the research centre

CREATION OF A COMPANY AS A MECHANISM FOR TECHNOLOGY TRANSFER
See pages (57-60)

QUESTION 7. WHEN SHOULD A COMPANY BE CREATED?

Key Issue: Key points to consider the creation of a Spin-off

Technology Transfer: all those agreements, irrespective of their legal status, which allow a relevant individual to obtain rights over knowledge, works and inventions created by another.

- Transfer subject to private regulation: Possibility of free negotiation between the two entities (direct award).
- Transfer subject to public regulation: Possibilities depending on the applicable regulations.

Technology Transfer by creating a new entity is a mechanism by which the research institution gets involved in the exploitation of research results. This model is currently being highly encouraged from governments and universities.

Possibility for researcher to participate in the capital and the activity of the company: Legal regulation and internal protocols. Need to prevent conflicts of interest.

Possible participation of research centre: Participation as a mechanism of compensation for technology transfer. Regulation of relations: Shareholders' Agreement

Key Issue: Dealing with partners having different profiles and interests, the Shareholders' Agreement

Transfer of shares regime: description of the regime that will regulate the mechanisms for transfer of shares, and define opportunities to plan divesture and /or participation in the sales opportunities:

- Pre-emptive rights from co-partners if there is an offer from a third party.
- Tag-along: all co-partners are allowed to participate in the sell in proportion to ownership
- Way out rights: if a co-partner wants to leave the company, the other partners may buy the shares under pre-defined economic conditions
- Better fortune clause: if an acquirer sells transferred actions at a higher price, the transferring partner is entitled to receive a predefined portion of the benefits.

Management and administration of the company

- Composition of governing body (research institutions not required to be members of the board)
- Rules for the adoption of agreements (major consensus, right of veto...)
- Right to information and auditing (system for monitoring the activity of the company)

Rules of conflict: procedures to follow in case of breach by either party

- Ways to compensate (e.g., compulsory sale of shares at a price below market)
- Arbitration if conflict in regards to interpretation or implementation of the Shareholders Agreement.

ANNEX I: CV

Ignasi Costas
Founding partner and head of the Innovation and Life Science practice of Rousaud Costas Duran SLP, a law firm with over a 100 professionals, with offices in Barcelona and Madrid. Expert in intellectual property, technology transfer, *new ventures* and venture capital. Member of the Board of Directors of several technology-based companies. Advisor to several public research organizations. Author of many articles related to his area of expertise. Lecturer at various Universities.

Alberto Ouro
Associate lawyer of the Department of Innovation of Rousaud Costas Duran, SLP. Law Degree from the University of Barcelona. Expert in innovation law and public-economic law.

Author of several articles and doctrinal publications about entrepreneurship and technology transfer from public research centres, among other subjects.

Roger Piqué
Roger, partner of Inveready Technology Investment Group. Wide experience in consultancy and startup financing. Prior to Inveready, he started his professional career at CIDEM, Industry department in CIDEM (ACC10 Catalan Government agency related to competitiveness and innovation), where he was responsible for creating the first business angels network in Spain and the development of the Catalan business angels network program, currently encompassing 7 networks and more than 400 active investors.

To date, his career has been closely linked to entrepreneurship and financing of high growth companies, being responsible for the organization of the first Business Angels courses in Catalonia, CIDEM's Investment Forums, the development of financial instruments and public programs for high growth companies, CIDEM's Venture Capital Program, Jeremie Program for Catalonia and various R&D Financing programs, among others.

Roger is a board member in various companies, including X-Ray Imateck, AQSENSE, PasswordBank Technologies, 3 Scale Networks, Neurotec Pharma, Lucierna, The Crowd Angel, Agile Contents and Adman Interactive S.L.

Jose Maria Echarri

Josep María is founding partner at Inveready and continues to be its largest private shareholder. He is considered as a world-class professional in promoting technology-based companies, driving the creation of the first integral support program to technological companies developed by the Spanish administration. Prior to founding Inveready, Josep Maria was the CFO and Business Development Manager for the Spanish biotech company, Oryzon Genomics,of which he is also a founding member and currently board member.

Additionally, as a consequence of his activity as a Business Angel and CEO at Inveready Seed Capital, he is the Board of several technology companies: Oryzon Genomics SA, Scytl Secure Electronic Voting SA, Aleria Biodevices SL, Proretina Therapeutics SL, Nanoscale Biomagnetics SL, MasMovil Telecom 3.0 SA, Palo Biofarma SL e Iahorro Unidos para Ahorrar, SL, and Yunait among others.

Josep Maria holds a BSc in Economics, Actuarial and Financial Science from the University of Barcelona and a Master in Financial Planning from ESADE Business School.

Pere Condom Vilà

Dr. Pere Condom is an industrial engineer and has a master's degree in business management. For the last 18 years he has been working on technology transfer, technological entrepreneurship and management of large public research infrastructures. Specifically, at the University of Girona he was responsible for technology transfer and he also directed the unit that supports the creation of technology-based companies. Later he was the director of the UPC Park at the Polytechnic University of Catalonia (UPC). He is currently director of the Science and Technology Park of Girona. He has combined management activities with teaching and research. Regularly he teaches masters sessions in several universities, lecturing on R&D management, innovation, technological entrepreneurship and promotion of regional economic development. His doctoral thesis was centered on technology transfer and on business creation models. He has conducted research and consultancy activities on projects related to innovation policy, science parks and technology investments. He has also published extensively on these same issues. He is in the board of directors of Inveready, a seed capital company.

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