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Expert Group Report

Management of Intellectual Property in Publicly-funded Research Organisations: Towards European Guidelines

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Expert Group Report

Management of Intellectual Property in Publicly-funded Research Organisations: Towards European Guidelines

Prepared by the Rapporteur Laura MacDonald
and the Chairman Gilles Capart
together with

Bert Bohlander, Michel Cordonnier, Lars Jonsson, Lorenz Kaiser, Jeremy Lack, John Mack, Cino Matacotta, Thomas Schwing, Thierry Sueur, Paul van Grevenstein, Louise van den Bos, Nicholas S. Vonortas

Directorate-General for Research
Knowledge Based Society and Economy

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Director : Jean-François Marchipont
Head of Unit : Isi Saragossi
E-mail : denis.dambois@cec.eu.int
Web site: http://europa.eu.int/comm/research/era/ipr_en.html

FOREWORD

This expert group on ”intellectual property issues in publicly-funded research” was organised by the Research DG of the European Commission, in the context of a series of activities supporting the European Research Area (ERA) activities and aiming at implementing the “3 % action plan”.

A group of external experts was invited to meet and discuss this topic, and to provide a set of recommendations regarding the management of intellectual property in publicly-funded research organisations, which could serve as a basis for the development of European guidelines. This report includes a review of the background, problem areas and current situation, and examines options for action by the public research organisations (PROs, including universities), industry and public authorities.

The expert group was also attended by members of the Commission services, who provided background information on relevant activities.

This expert group report was written and assembled by the Rapporteur and the Chairman, with the aid of all group members and the Commission officer responsible.

DISCLAIMER: Although members of the Commission services participated in this expert group and provided assistance in assembling this report, the views expressed both individually and collectively in this report are those of the external experts, and may not in any circumstances be regarded as stating an official position of the European Commission.

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THE EXPERT GROUP

Bert Bohlander	UNITE (Universities International Team of Experts) *Chairman* VSNU (Dutch Universities) *Adviser*
Gilles Capart *(Chair)*	Sopartec S.A., Belgium, (Technology Transfer Company of Université catholique de Louvain), *Chief Executive Officer* ProTon-Europe network of Transfer Offices from Public Research Organisations, *Chairman of the management Board*
Michel Cordonnier	Technological University of Compiègne, France *Director, Economic Development*
Lars Jonsson	Holding Company at Uppsala University, Sweden *General Manager*
Lorenz Kaiser	Fraunhofer Society for the Application of Applied Research, Germany *Director, Legal Affairs*
Jeremy Lack	Medabiotech S.A., Switzerland *Director and General Counsel*
Laura MacDonald *(Rapporteur)*	University of Edinburgh Edinburgh Research & Innovation Limited, U.K. *Business & Commercialisation Manager*
John Mack	Astra Zeneca, U.K. *Global Patent Licensing Manager*
Cino Matacotta	Consiglio Nazionale delle Ricerche (CNR), Italy (responsible for the "Office for the valorisation of research results")
Thomas Schwing	IMG Innovations-Management GmbH and Innovation Relay Centre (IRC) Hessen/Rheinland-Pfalz, *Director*
Thierry Sueur	Air Liquide, France *Vice President, European and International Affairs and Intellectual Property*
Paul Van Grevenstein	ASTP – Association of European Science and Technology Transfer Professionals, *President* STI Management and Adviser technology transfer Leiden University Medical Centre, *Adviser*
Louise van den Bos	Technology Transfer & Licensing, Erasmus University Rotterdam, The Netherlands, *Director*
Nicholas S. Vonortas	Professor of Economics and Director of the Centre for International Science and Technology Policy, The George Washington University, USA; Visiting Professor, National Technical University of Athens, Greece.

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- Mr. Denis Dambois, Unit K1

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- **DG Enterprise:** Mr. Christian Lettmayr
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EXECUTIVE SUMMARY

This report summarises the opinion of a group of experts (the Group) assembled by the Directorate-General for Research of the European Commission on the management of Intellectual Property Rights (IPR) deriving from public funding in order to promote innovation at European level.

The report is directed primarily at research universities and research centres funded by publics funds (collectively Public Research Organisations or PROs) to help them identify the processes, good practices and the implications of a more active involvement in the innovation process through the management of IPR and other policies and tools such as interaction with industry and the creation of new companies. The discussion and recommendations are believed to be of interest also to the other parties strongly involved in the process, namely the researchers, the industry partners, the entrepreneurs and the policy makers.

The majority of basic research in Europe is conducted by PROs. They have always been an important source of innovation. The report reviews the knowledge transfer processes and their evolution over the last 30 years. The processes evolved from an **"Open Science"** model in which the PROs did not retain any intellectual property rights (IPR), to a **"Licensing Model"** in which the PROs started to retain, protect and commercialise inventions based on their discoveries, essentially through licensing the IPR to industry or to start-up companies. The Licensing Model has been very successful in the USA, in terms of number of patents, license revenues, new products, new companies and new jobs, but has not been nearly as successful in Europe, primarily because of a more fragmented market and a lower density of research based companies headquartered in Europe. Both models can be considered as linear models of innovation.

However, over the last ten years, a third model, which we call the **"Innovation Model",** has started to develop in Europe. In this model, the Licensing Model, which is still important, has been supplemented by a more active policy of collaborative research with industry, in particular through EC Framework Programmes, and by a pro-active involvement in the creation of spinout companies. The results are comparatively more important at regional level and have been encouraging so far in the countries where it has been applied to a significant level. The Innovation model is consistent with the "interaction" or "systemic" models of innovation, which are considered more effective. **One of the main policy recommendations of our Group is that the adoption of the Innovation Model by European PROs should be encouraged as the most effective way to produce significant socio-economic benefits at European level from publicly funded research results.**

The common feature of the Licensing Model and of the Innovation Model is the identification, registration and management of an intellectual property pool from which the various innovation models can draw. Ownership of the research results and of the inventions deriving from them used to be fragmented across the various funding organisations, mostly governmental. **The Group considers that the best practice is to vest initial ownership of results and inventions funded by public funds to the PROs where the research has been conducted.** This has been recognised by several studies and by an increasing number of countries, which have passed specific regulations to that effect. This policy should be extended at European level. The issue of ownership of results funded in part by industry remains a debatable issue, which can be resolved by further discussions between industry and PROs. The issues of joint ownership are being addressed as well, because of their increasing importance for collaborative research.

The differences between the IP regimes of the European Countries are significant in many areas, including the definition of service inventions, the scope and extent of research exemptions, the professors privileges, the compensation of inventors and the joint-ownership regimes. **There is a need for convergence and harmonisation of ownership regimes at European level.** For the time being,

professionals of PRO transfer offices need be aware of those differences before deciding on applicable law.

The straight licensing of IPR to existing companies or to new companies, without protracted involvement of the PRO in the development of the potential applications, remains one of the main forms of knowledge transfer. This process is relatively straightforward and several specific guidelines are recommended to ensure that licence terms are consistent with the missions of the PRO, including ultimate benefit to the general public. **All stakeholders need to have realistic expectations about the value of the IPR.** As an alternative to up-front payments or royalty-bearing licences to spinout companies, the PROs may consider receiving stock from or assigning title to spin-out companies.

Collaboration with industry may take many different forms that are potentially beneficial to both parties and these should be encouraged. Many of these forms are already present in the Open Science Model. Distinction should be made between contract research, wherein no IPR are generated or retained by the PRO, and collaborative or sponsored research, wherein substantial IP is generated by the PRO and may be retained as a basis for further research and collaboration with the same or other partners. **The further development of collaborative research on fair and equitable basis is one of the essential components of the Innovation Model.** It is one of the ways by which proof of principle and demonstration of economic utility of PRO inventions and know-how can be funded with both industry and public financial support, such as in the EC Framework Programmes. The report reviews some of the practical issues faced by PROs when negotiating collaborative research and consortium agreements with industry and makes some recommendations. Certain issues remain debatable and should really be resolved on a case-by-case basis between the parties. **The Group recommends that mutually acceptable guidelines be developed by common agreement between representative associations of industry and PROs with a view to arrive at recommendations of good conduct, which will facilitate and expand collaborative research opportunities.** A tentative set of guidelines of collaborative research addressing the issues of ownership, use rights, access to background, management of IPR and compensation is submitted as a starting point.

As we have seen from US experience over the last twenty years, rejuvenation of the economy and the development of a knowledge-based economy, as envisioned by the EC, can be fuelled in part by the creation of more new technology-driven companies. In addition to a strong technology basis from the PROs, the US recipe contains a large domestic market, a strong entrepreneurship culture and strong backing by venture capital. For these reasons, the creation of a large number of university spinout companies has been almost spontaneous, without much active direct involvement from the PROs themselves, beyond the conclusion of licence agreements. By contrast, in Europe, the spontaneous creation of PRO spinout companies has occurred at a much lower pace. For the past ten years, several European PROs have embarked upon ambitious programmes of assisting the creation of spin-out companies involving a combination of several policies, including training of entrepreneurs, incubator facilities, coaching, seed capital. The results support the opinion of the Group that the rate of creation of spinout companies can be significantly increased. **The Group recommends that the policy of active involvement of PROs in the creation of sustainable spinout companies be further encouraged at European level by a number of public policies and support, including downstream support for these companies after they have left the nurturing environment of a PRO**. Recommended practices are reviewed.

Successful implementation of the Innovation Model of knowledge transfer in European PROs is a big challenge. Why should European PROs embark on such a challenge? The main reasons are reviewed. While generating additional revenues for the university may be useful, this objective should not be the driving force behind adoption of such a proactive policy regarding IPR. Except in rare circumstances, the policy will not be self-sustainable. **Given that the mission of a PRO includes promotion of socio-economic benefits to society arising from the research undertaken in the PRO, then such a policy is essential. The Group considers that the active involvement of European PROs in managing its IPR is not in conflict with its education and research missions, but will become a**

key consideration in attracting students, scientists and further research funding as well as supporting the mission of disseminating research results.

In practice, implementation involves establishing access to a dedicated, professional, adequately resourced and experienced Knowledge Transfer Office (KTO), which may take several forms and may involve a wide range of activities. The missions of the KTO must be very well defined and the objectives must be realistic. Both must be unequivocally endorsed by the PRO management and supported by the researchers. They must be communicated and explained to all the parties involved, industry, government and the public**. There must be a firm, long-term commitment to providing the necessary funds for the establishment and operation of a professional Knowledge Transfer Office (KTO).**

The report reviews the practical issues in defining the objectives, the missions, the functions, the funding and the resources of the KTO and makes recommendations on how they can be resolved. Clearly, the job of technology transfer officer is particularly challenging and requires a very broad set of skills as well as exposure to industrial experience. It will inevitably take many years for a KTO team to accumulate the skills, knowledge and experience for the job**. This time can be shortened by supporting the development at European level of a federation of professional associations of knowledge transfer professionals in order to share experience, disseminate the good practices and tools and providing continuous professional development and training.**

CONCLUSIONS AND RECOMMENDATIONS

For Public Research Organisations (PROs)

1. **Without abandoning the Open Science Model, PROs should seriously consider taking a pro-active role in the innovation process by managing IPR arising from research results. This is an important strategic decision, which requires establishing a clear mission, realistic objectives, appropriate resources and a dedicated professional transfer office.**

2. **The main objectives should be to maximise the benefits of publicly funded research for society. These benefits can be measured in terms of regional economic development, new products, new companies, new services, new jobs and improved quality of life.**

3. **The returns for PROs are to be measured in terms of attracting more students, retaining good scientists and enhancing access to additional research and development funding opportunities. Securing guaranteed levels of additional funding through licensing is not realistic and should not be a prime objective.**

4. **In Europe, creating and licensing IPR is not sufficient in itself to produce significant benefits. There is a need for a much stronger interaction between PROs and Industry and for a more active involvement in the creation of new technology companies**

5. **The KTO responsibilities must be exercised in a professional way and require training and experience that includes an understanding of the needs of the researchers and of the legal, intellectual property and commercial issues surrounding the development of technologies. It can take many years for the necessary experience to be gained and so PROs should encourage membership of professional KTO networking associations in order to exchange good practices and provide training.**

For Industry and PROs

6. **The objectives of further developing a knowledge economy can only be achieved through a much closer collaboration between PROs and Industry. Both parties should consider revisiting their relationships with a view to maximising the mutual benefits that may accrue when PROs are enabled to take a more active role in the innovation process.**

7. **Industry and PRO associations should develop and implement by mutual agreement voluntary codes of conduct and guidelines to optimise the opportunities for a range of strategic relationships that can be entered into. Both of these key stakeholders should recognise the mutual benefits that such interactions can yield.**

For policy makers

8. Most of the early stage research in Europe is performed within PROs and most development is performed by Industry. Both are necessary to the knowledge economy and should be supported by public policy. The improvement of the knowledge transfer from Science to Industry should be a top policy priority.

9. The European countries that have not done so already should consider enacting regulations on the use of the results of publicly funded research. The principle of assigning to PROs ownership of results and first right to inventions should be recognised as good practice.

10. Since the benefits from knowledge transfer from PROs are mainly societal and since any financial returns are likely to arise only after a long-term involvement in the activity, it is important that KTOs be financially supported by several funding sources, including public authorities.

11. Intellectual property laws differ to a significant extent between European countries and should be harmonised.

12. Some Member States have successfully experimented with new policies and tools in order to encourage the knowledge transfer from PROs, including subsidies, tax incentives, seed capital funds, incubator facilities, etc. Best practices should be reviewed, disseminated and any lessons drawn could then be implemented

1. CHAPTER ONE

Background Reasons and Rationale for the Management of IPR

The first chapter of the Guidelines identifies policy issues around the management of intellectual property rights in PRO's. The aim of the introduction is to set out the rationale and reasons for pro-active management, together with the benefits and objectives, which need to be committed to by all stakeholders in the process.

Key Messages

There is consensus among all stakeholders with an interest in innovation that more should be done to facilitate effective management of IPR and technology transfer from PROs.

There is evidence from different legal and practical regimes such as the US and the UK that effective management of IPR (the innovation model) can lead to substantially increased economic and societal benefits.

The open science and innovation models for the management of PRO research results can simultaneously operate to good effect within a PRO.

PROs should be given support to develop the access to the necessary expertise in IPR management and exploitation.

Unless researchers understand and accept that their PRO mission to promote the dissemination of research results can be enhanced by the innovation model, it will be impossible to increase technology transfer from PROs.

1.1. Introduction

Innovation has an impact on macro-economic level as well as on micro-economic level and therefore impacts on the lives of everyone. There is therefore a particular range of individuals with a role to play in economic matters to whom innovation management is of direct concern and interest- these we refer to as our stakeholders and they are more fully identified below. Building awareness about the steps that together we can pro-actively engage in to harness the maximum benefits from innovation is recognised as a crucial exercise as we enter a new century.

The basis of interaction between academia and industry is changing from the more historical scenario where new technologies were pushed out from the PROs' side to one where the marketplace exerts a pull on technology it now wishes or needs to access from academia. In order to increase this exchange, PROs can do more than just establish technology transfer organisations: they can also increase awareness within the research base about the bigger picture of how research activities can be turned into economic and societal benefits.

1.2. The Fundamental Role of PROs – The Review and Debate.

It is important for everyone to understand how the financial support for research and development is provided for. While individual national systems may vary, the common theme is one where by necessity there is a selection process to support science. However, at present there appears to be a lack of awareness amongst researchers in PROs that the goal of carrying out research, which is to provide ultimate benefits to society, can only be achieved in an optimal way where there is additional support of a pro-active, professionally managed technology transfer function. This consensus of opinion is shared both by PRO and industry members.

The assessment of science as carried out in PRO's is under review across Europe. In the future additional and different criteria may be applied. The "publish or perish" traditional route in some places is no longer the exclusive basis of assessing the validity of good science. For example, there is a changing picture in both The Netherlands and the UK with regard to the research assessment exercise where industrial applicability of research results may become a formal performance metric.

Motivating and rewarding PRO researchers ought to involve a recognition of their ability and experience in collaborating with industry at a research level as well as transferring technology. In The Netherlands, the review criteria have already changed from being on publications only to looking at broader results, including obtaining support from sources other than public funding. Industrial members of the Group confirm that, in addition to published information, there is a wealth of know-how and unpublished information, which is of use and value to new technology and which also comes from PROs. The role of the TO should be to stimulate awareness of the availability of this type of information and make it available to industry as well.

However, there remain ideological concerns about the future of research in academia. Many researchers do not believe that it is ethically acceptable to obtain financial benefits from academic research results. Therefore, key topics to be discussed within PRO's (and with their sponsors) include the question of motivation of PRO researchers to engage in both research and commercialisation of their results as well as the question of how to handle financial revenue which may accrue as a result of such commercialisation.

The commitment (or a lack thereof) by the institutions themselves to the commercialisation process causes problems and ought to be addressed. There needs to be an institutional buy-in to the whole concept of technology transfer such that the objectives and mechanisms are transparent to all. Clear support must be given to enable a technology transfer culture to become an intrinsic part of the PRO's activities. In many member states this is being referred to as the 'third mission' of a university, alongside research and teaching. There is a worldwide awareness of this whole topic, as evidenced by the recently published Report commissioned by the *OECD*[1], which gives us a detailed description of the global political environment for technology transfer activities.

1.3. The European Imperative

At the Lisbon European Council (March 2000), the European Union established the objective "*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.*" In achieving this objective, research, technological development and innovation are called to play a key role.

[1] OECD Report " *Turning Science Into Business: Patenting and Licensing at Public Research Organisations*" April 2003 – http://oecdpublications.gfi-nb.com/cgi-bin/OECDBookShop.storefront/EN/product/922003021P1

The R&D spending (GERD) in 2002 in Europe[2] (15 countries) was running about 1.93% of Gross Domestic Product (GDP), whereas in the US and Japan the funding was respectively 2.69% and 2.98% of GDP. The average annual rate of growth of GERD since 1995 (0.32%) has been trailing that of the US and Japan (1.53% and 1.83% respectively). One of the key policies is to increase R&D spending to 3% of GDP by 2010 as announced in the Commission's recent Action Plan[3] where two-thirds of the investment is to be provided by the private sector.

One third of all R&D activity is funded by public sources, while PROs carry out even more research as a result of receiving additional sponsorship from charities and the private sector. Keeping in mind that development, which is almost the exclusive domain of industry, is relatively more expensive than research, it can be inferred that the relative importance of PROs in early stage research is predominant.

The contribution of useful research from PROs to economic and societal benefits is staggering. According to a study from the National Science Foundation, 70% of all patents filed in the US cite PRO research results as their basis. The economic importance of those discoveries has not escaped the attention of the governments and is often advocated to justify additional funding. The Third Report on Science and Technology Indicators[4] describes a (r)evolution of the university system and notes that industrial change and changes in public policy are putting PROs under pressure for a more effective university-industry cooperation.

The relative importance of PRO-based research is likely to increase in the future because of the following trends:

- Industrial companies are concentrating on core business and short term profitability;
- New products and services increasingly involve cross technology approaches;
- It is increasingly difficult for companies to cover all the new fields they wish to invest in;
- The reduction in time lag between novel technology being discovered and then having new technologies on the market based on such novel ideas.

This trend is also evidenced by the fact that many companies are progressively outsourcing a significant share of their basic research to PROs in order to benefit from their expertise, infrastructure, low costs and background technology.

Interesting data can be found showing the interaction between PRO research activities and technology transfer by looking at the USA figures as compiled by the Association of University Technology Managers (AUTM) [5] and a UK study co-ordinated through Nottingham University[6]. Such studies would appear to indicate that, with a more proactive stance, there could be additional financial, societal and economic benefits from effective technology transfer management.

While the management of IPR by European PROs has improved significantly over the last 10 years, there is currently no comprehensive survey, which might permit evaluation of the effects. Limited information is available from certain countries. The degree of implementation varies considerably from North to South and from West to East. On average, Europe is lagging considerably behind the

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[2] Key figures 2002, *Towards a European Research Area*, ISBN 92-894-4205-0 – ftp://ftp.cordis.lu/pub/indicators/docs/ind_kf2002.pdf

[3] Commission of the European Communities *Investing in Research : An Action Plan For Europe* COM(2003)226 – http://europa.eu.int/eur-lex/en/com/cnc/2003/com2003_0226en02.pdf

[4] European Commission DG Research Third European Report on Science & Technology Indicators, 2003, ISBN 92-894-1795-1 – http://www.cordis.lu/indicators/third_report.htm

[5] AUTM: *Licensing Survey: FY 2001* published 2003 – http://www.autm.net/surveys/01/01summarypublicversion.pdf

[6] Nottingham University Business School *Annual UNICO-NUBS Survey on University Commercialisation Activities - Financial Year 2001*, 2002 – http://www.nottingham.ac.uk/business/research/TechTransfer

USA in this respect. Japan started late but is developing a network of approved TOs funded by public subsidies[7].

1.4. The Models of Knowledge Transfer from PROs

Before discussing the various aspects of knowledge transfer from PROs and how this transfer may be improved in order to promote innovation for the general benefit of the public, it is useful to understand the evolution of the different models of knowledge transfer over the last thirty years.

The various processes, which have been developed in order to bridge the gap between research and development, are represented schematically on figure 1.

[7] Presentation by Y. Tsukamoto at the TIP workshop on the Management of Intellectual Property Rights from Public Research on December 11, 2000 – http://www.oecd.org/dataoecd/13/39/1903874.pdf

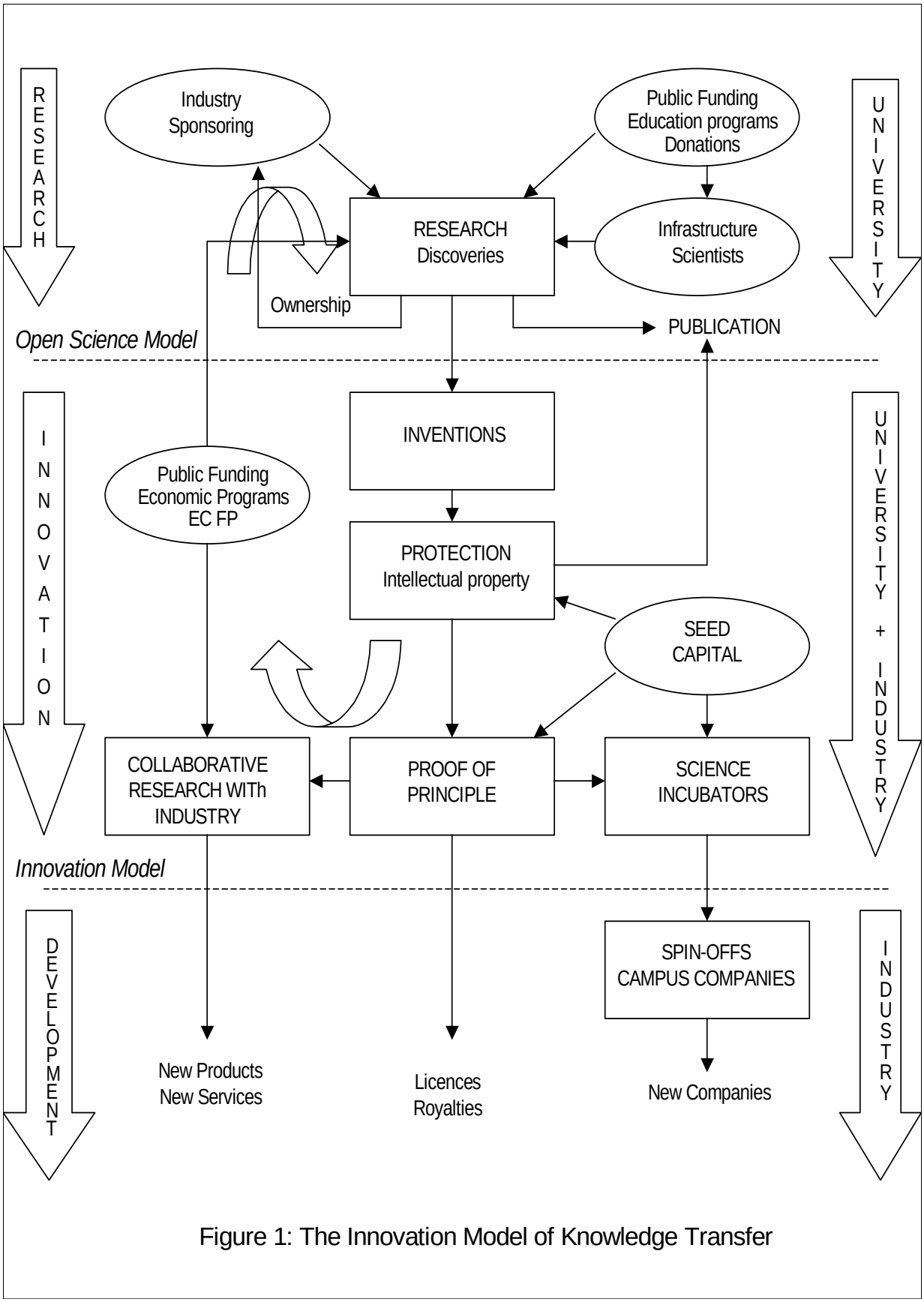

Figure 1: The Innovation Model of Knowledge Transfer

1.4.1. PROs as sources of new discoveries - The Open Science Model

Although there is a long tradition of interaction between industry and academia as more fully described in Chapter 4 below, it can be stated that traditionally, PROs have been recognised as sources of innovation through two main routes:

- *Publications of research results in scientific journals*. As soon as published, they enter the public domain and can be used by anyone.

- *Contract work from industry* in which PROs have contributed to the development of new technologies. In most cases, industry contracts to acquire ownership of the results and files patent applications to protect its development.

These are illustrated schematically on the top panel of Figure 1.

In both cases, no intellectual property rights are retained by PROs (other than moral rights linked to the authors). We call this model the "Open Science" model because it is comparable in many ways with the open source model in software development. The only moral obligations from the users are to acknowledge credit to the source and to share the improvements. There is no need to manage intellectual property rights, since PROs do not retain them, and there is correspondingly no need for technology transfer offices. Innovation is entirely left to the responsibility and diligence of private industry.

The Open Science Model is very appealing to scientists because it accords a universal value to science and the unrestricted flow of new information[9]. The quality and reputation of researchers is measured by the number and quality of peer-reviewed publications. It was the prevailing model in the USA until the 1980s and still prevails in most countries of Europe as the traditional basis of transferring PRO research results to the public.

1.4.2. PROs as Sources of New Inventions - The Licensing Model

The US Experience

In the USA, prior to 1980, inventions based on university discoveries funded by public money belonged to the US government, which had the policy to grant only non-exclusive licenses. In practice, there was little incentive on the part of researchers to file patent applications and little incentive on the part of industry to take non-exclusive licenses from the government.

The Bayh-Dole Act[8] strongly encouraged PROs in receipt of research funding from the Federal Government to establish a technology transfer function. The major features of the law[9] are:

- Title to inventions sponsored by the Federal Government are with the university, unless the university chooses not to take title;
- If the university elects to take title, it must file for patent(s) and show due diligence in finding a licensee that will develop commercial products;
- The university must share a portion of royalty income with the inventor;

[8] *The Bayh-Dole Act. A Guide to the Law and Implementing Regulations*" http://www.ucop.edu/ott/bayh.html

[9] Some of these provisions, such as the march-in rights and the obligation to manufacture domestically have been questioned by both industry and PROs.

- The Federal Government is granted a royalty free non-exclusive license for Government procurement purposes only;
- The government retains march-in rights to undertake commercialisation if the contractor is not fulfilling obligations as specified in the Act;
- Preference in licensing is to small businesses;
- If an exclusive license is granted in the United States, the licensee must agree to "substantially manufacture" the licensed product within the United States.

As almost two-thirds of research funding for US PROs is from the Federal Government, this Act had a serious impact on the behaviour of PROs. Since the stated purpose of the Act was to facilitate the transfer of technology for the public use and benefit, adoption of this statement as a primary mission for the ensuing TOs is not surprising.

Since the passage of the Act, most US PROs have created a Technology Transfer Office (TO) which concentrates mainly on the central stream of the Innovation process depicted on Figure 1, namely the cycle encompassing Invention Disclosure, IP protection and Licensing.

The results have been quite encouraging. The US Association of University Technology Managers (AUTM) estimates on the basis of the FY2001 survey that in that year at least 358 new products were introduced to the market under license from PROs. Without direct involvement of PROs in the patenting-licensing process perhaps fewer than half would have been developed. Earlier AUTM surveys attempted to measure a wide range of benefits, including spin-outs based on university technologies, local and government taxes raised, all of which activities could be attributed to this new PRO function.

In conclusion, as a result of many factors including the Bayh-Dole Act, a proactive approach to the management of IPR by PROs appears to have stimulated more patenting activity, more company formation and an overall positive impact on the economy.

The European Experience

Traditional technology transfer by PROs has always sought to ensure that potentially exciting new technologies were offered to industry. But in reality, while there have been successful examples of new products arising from PRO research, there is evidence to suggest that the volume of actual research ongoing in European PROs should be leading to a far greater number of technologies being developed in an industrial context. Studies in both the US and Europe have shown that there is a correlation between levels of research activity and opportunities for new technologies. (See Chapter 4 below.)

It appears that without some pro-active management by PROs there is simply no way that industry is able to find out about and invest development funding in all the opportunities available. Industrial members of the Group declare that in their opinion and experience, industry benefits if PROs manage new inventions because industry is more likely to become aware of them. There is an increased likelihood that in partnership, PROs and industry will identify funding opportunities to develop early stage ideas. It is also recognised by industry that for truly novel platform technology with no clear routes to market, then an appropriate way to move ahead is often to identify high risk investment funding sources such as venture capitalists so the route to market may be a new company.

For PRO inventions to be given a reasonable opportunity to be developed, it has been observed in Europe that it is rarely sufficient for the PRO to simply file patent applications and secure industrial development funding at that stage. It is often necessary to participate actively to the demonstration of the proof of principle of the potential utility of such inventions before they are adopted by industry.

In Europe, only a few countries have thus far chosen to stimulate proactive knowledge transfer by adopting specific laws concerning ownership of public research results and have encouraged the

creation of TOs for patenting and licensing inventions based on university discoveries. Those that have (including Denmark, Germany and France) have done so only recently. Thus far, in a comparative review of performance, although the scientific productivity measured by the number and quality of scientific publications is comparable, the average licence revenues are one order of magnitude less than in the USA.

For all these reasons, it is appropriate to recognise that management of IPR by PROs is essential. Therefore we need to look beyond the traditional Open Science model and beyond even relying upon traditional licensing activities.

1.4.3. PROs as a source of innovation : The Innovation Model

There are two main routes available to PROs to demonstrate proof of principle i.e. that research results have identified a potentially useful invention:

- *Collaborative research with industry*. In exchange of attractive license option rights on the university background technology, which may contain not only patents but also know how, the industry partner will fund the incremental research leading to the proof of principle, often with public development grants. Programs funded by the European Commission have further supported this model in Europe, which generally impose in addition the presence of partners from several European countries for wider market access. In the USA, the government is supporting a similar scheme under e.g. the CRADA programs.

- *Creation of Spinout companies*. PRO technology may form the base for creating a new activity. The technology is then made available at attractive conditions under license for consideration of shares and/ or royalty stream. This requires an additional role in finding entrepreneurs and seed capital. In some cases virtual capital may become available under the form of interest free loans or SBICs. Typically, the early years of operation will be devoted to verifying the technical feasibility of the concept (proof of principle) and the market potential. Regional governments and PROs are actively supporting this route because the new companies tend to remain in the vicinity of the originating PRO and contribute to the rejuvenation of the local economy. Once the proof of principle is achieved, the new companies enter the development stage and other sources of funding become available.

These two additional processes are illustrated on the left and right side of the innovation stage panel illustrated on Figure 1. In both cases, PROs are contributing directly to bridging the gap between research and development, hence the reference to the more comprehensive term of "innovation" model. The TOs need to master a wider range of tools and services beyond patenting and licensing, including business development, coaching, incubator facilities, seed capital funds, science parks, etc. Their staff need to be more experienced and should include professionals with industrial experience. Thus the Innovation Model describes the process wherein there are policies and resources in place to enable PROs to navigate IPR through the wide range of exploitation avenues that are possible.

There is an additional dimension to this process. The Open Science and the Licensing models can be characterised as "linear" models, viewed as a continuous processes from discoveries to useful applications, either driven from the Science or from Industry needs (contract research). The recent theory of innovation[10] [11] shows that effective innovation is not a linear process and should involve

[10] Leydesdorff, Dr Loet and Cooke, Philip and Olarazan, Mikel (2002) Technology Transfer in European Regions: Introduction to the Theme Issues. Journal of Technology Transfer 27(1):5-13 – http://dlist.sir.arizona.edu/archive/00000105/01/index.htm

[11] Kline S.J. and Rosenberg N, (1986) An Overview of Innovation, in Landau R. and Rosenberg N., *The Positive Sum Strategy*, pp. 275-305.

feedback and frequent interactions at different levels between Science and Industry. This is one of the goals of the Framework Programs sponsored by the European Commission.

This observation is further reflected in the revised definition[12] of innovation as being "*the conversion of new knowledge into economic and social benefits – now acknowledged to take place as the result of complex long-term interactions between many players*". This is exactly what the Innovation Model sets out to achieve.

The Innovation Model is comparatively more developed in certain European countries, notably the UK, Scandinavian countries, Netherlands and Belgium, than in the US. The potential benefits for the public and for the university will also be larger and more regional in character.

One of the consequences of this difference is that the metrics developed to measure the efficiency of the knowledge transfer process should not be limited to the patenting and licensing cycle but should also capture the importance of collaboration with industry and the assistance in the creation of new companies.

1.5. The Way Ahead – An Innovation Model *in parallel with* the Open Science Model

The "Open Science model" has proven very effective in fostering the advancement of science and knowledge. It is probably more appropriate for fundamental or basic science and social sciences. In certain instances where the technology has far reaching implications and where the risks of misappropriation by private interests are detrimental to the public, the open science model can even be the most effective to promote innovation. IPR management has a very limited role to play here.

On the other hand, there is substantial evidence from the surveys conducted by the Association of University Technology Managers (AUTM) that the progressive implementation of the "licensing" model in the USA since 1980 has produced substantial returns to the US economy in terms of new products, new businesses and employment. It is estimated that at least half the new products based on university patents would not have been developed if the results had been put in the public domain without patent protection.

The recently published OECD Report[13] demonstrates that mere application of the licensing model has not been able to generate the same level of financial or economic results as in the US. There are a number of reasons for this and these are explored in more detail in later chapters. On the other hand, certain PROs have pioneered the implementation of the innovation model with conclusive evidence of success in terms of increased new company generation, enhanced relations with industry and licensing activity. The two models are actually complementary and should be supported. By the same token, it would be a mistake to orient all research conducted at PROs to short or medium term economic applications. PRO's should seek to strike a balance between the two models thus ensuring that IP generated from public funding which has potential economic or social applications is managed in a professional manner.

[12] The October 2002 special edition of Innovation & Technology Transfer includes a very useful glossary of terms; www.cordis.lu/itt/itt-en/02-spec01/glossary.htm

[13] Op. cit.

2. CHAPTER TWO

The Challenge of Managing IPR in a PRO

If there are to be benefits accruing to society from IPR management, then we must explore ways to harness the best of the Open Science model along with the benefits afforded by implementation of the Innovation Model for inventions arising from PRO work. While the traditional role of carrying out fundamental research in a PRO is a clear function, latter day thinking is recognising that PROs can have a far greater impact on the economic and qualitative aspects of life. In other words, there are limits to the traditional forms of interaction with the outside world so we can begin to address ways to achieve even greater efficiency in the core mission of disseminating new knowledge.

Key Messages

A culture of awareness of IPR needs to be stimulated among the research community in PROs in order to enable identification of inventions.

PROs and their researchers must be allied in the goal of promoting knowledge transfer.

Initial ownership of results and inventions obtained by PROs should preferably vest with such PROs provided that they have the capability to manage and diligently exploit them.

The IPR portfolios of PROs should be managed in a highly professional manner, (including ensuring mutual respect for valid third party IPR) if the IPR is to be useful to industry.

Harmonisation across Europe of regulatory regimes for IPR matters should be promoted rapidly.

There are resource implications, which the PRO needs to address if the portfolio is to be effectively exploited, and there should be more public funding to support this function.

2.1. Overview of the Management of IP in PROs

Innovation requires effective management of IPR. There needs to be a culture where the inventions arising from research results can be identified and managed. Identification requires education (of researchers and TOs), while management of the IP requires addressing issues of ownership and sponsorship obligations. This chapter will demonstrate the key areas for action, including:

(1) Education: cultural awareness to change the expectations of the PRO scientific community needs to be introduced;
(2) Ownership: ownership of the research results must be clearly established;
(3) Management: responsibility for IPR needs to be centralised with the PRO;
(4) Professional approach to the management of the IPR portfolio is essential;
(5) Respect for Third Party IPR: “do as you would be done by”;
(6) Harmonisation of legal regimes: to encourage more efficient technology transfer.

2.2. Ownership of Research Results, including Inventions

While there is a wide divergence of statutory legal regimes governing ownership of inventions across Europe, we can see several trends and practices as follows. The ownership of the results from public funded research is governed by three different types of regimes, namely 1) employment and IP related legislation, 2) Government Research regulations, which of course vary from country to country and 3) contractual arrangements with industrial sponsors.

Ownership under employment and IP-related regulations.

IP - related legislation in Europe generally identifies three types of invention. Firstly, we see *service* inventions, when the act to invent is a function covered under the employment agreement. Secondly, we see *free* inventions, which are made independently of the employment arrangements by relying in no way on the resources or expertise of employment. Thirdly, we see in some countries the concept of *dependent* inventions for inventions made outside the scope of the employment agreement but making use of information, materials or equipment owned by the employer.

From a review of European territories it can be observed that all countries assign the service inventions to the employer, although the definitions of service inventions vary to some extent from country to country. Several countries include the right to a fair compensation to the employee inventor. This model is predicated on the needs of industrial companies that invest in research and development as one of their main sources of competitiveness.

When this ownership regime is translated to PRO-based research, the general principle is not easily applicable for several reasons:

- In certain European countries, many researchers are not actually on the "payroll" of the university, but are sponsored directly by government grants, while the general infrastructure where the research is conducted belongs to the university;

- Students are often involved in research activities but are neither employed nor actually compensated. Sometimes national law describes their work as falling under the category of dependent inventions;

- In PROs, the researchers are compensated for doing research and making discoveries. Most researchers would claim that they are actually not compensated for making inventions, which is going one step further, namely conceiving useful applications of their discoveries and reducing them to practice. They do not feel obliged to manage or transfer inventions and consider that they are generally free to publish in the public domain without much control.

- Professor's privilege exists in several territories and this means that ownership of results and inventions lies with the research team, not with the PRO employing them.

In the "open science model" the results from the research are quickly published and enter the public domain. The issue of ownership is resolved at that point since nobody "owns" those results anymore.

If, on the contrary, it is intended to protect the results and the inventions as trade secrets or patent applications for further development, the issue of establishing ownership becomes critical. No party will invest significant funds to develop an invention where ownership is questionable.

In practice, there must be at one stage a single party concentrating the ownership rights (or at least first option) in order to be in a position to exploit the inventions i.e. to grant licences or to assign ownership for exploitation purposes. The most logical route is to concentrate those rights by vesting first

ownership in the PRO where the research actually takes place. To be absolutely secure, this requires the implementation of a number of legal instruments, namely:

- for scientific and academic personnel paid directly by the university, the employment agreement must make clear that ownership of (or first option to) research results and inventions made in the normal course of their employment belong to the university or PRO. A good practice is to incorporate by extension into the employment agreement a general university regulation assigning to the PRO ownership of the research results and inventions made by employees, describing the diligence commitments taken by the university to commercialise the inventions and allocating the net revenues between the inventors, their research units and the university. If the PRO fails to protect or exploit, those rights may revert to the inventors;

- scientists paid by research grants, the visiting scientists and the students should agree in writing, preferably before starting a research project, that their contributions to the results and inventions are assigned to the PRO, in exchange for them becoming eligible under profit sharing schemes to share the returns of successful exploitation;

As regards students, some PROs in the UK have attempted to impose such conditions at the time of enrolling the students. This practice has met with much criticism. Since the IP in question relates to the research activities of the PRO, there should be a distinction drawn between undergraduates (who are there to learn) and students, particularly postgraduates, who may be involved in carrying out research. For this latter category, a more acceptable practice is to request students (and external scientists) to sign an assignment or an irrevocable option to the assignment of their share of ownership in commercial results and inventions before joining a research project. In all cases, the PROs must ensure adequate protection of the freedom of academic personnel and students to publish the results of their investigations. This could be managed by setting a limited review period to identify protectable results (such as 60 to 90 days) to enable the PRO to seek patent protection.

Ownership under Government Research Regulations

Even though the IP rights on the research results and inventions may initially vest in the PRO where the research has been conducted, either by statute or pursuant to specific internal regulations adhered to by the employee and other researchers attached to the PRO, there are circumstances where ownership of the IP may not ultimately remain with the PRO.

This is the result of the nature of public research funding conditions in Europe where ownership may pass to a research sponsor as a condition of funding. No distinction is generally drawn between the results of the research and commercially applicable inventions. Considering that most of university research is funded externally and that different parties could fund successive stages of research, the net outcome of this principle is that ownership of the results and inventions could be legally disseminated among several governments and private parties. In practice, this makes it very difficult to trace the ownership of certain technologies and jeopardises the ability of the technology to be managed or exploited at all. Since several parties could conceivably claim joint ownership, exploitation becomes almost impossible.

In the US until 1980, the general rule was that the inventions made in the course of research sponsored by the government belonged to the government. The finding that this system was inefficient led to the enactment of the Bayh-Dole Act[14]. The current debate in Europe resembles much of the US history in this area. It was observed that neither the government nor the public authorities administering the

[14] See for example the historical overview made by Howard W. Bremer: *University Technology Transfer: Evolution and Revolution*. – 1998, Council On Governmental Relations – http://www.cogr.edu/docs/Anniversary.pdf (p. 13)

research agreements were in a position to effectively manage IP and to market licences, which were often non-exclusive and attracted little interest. The Bayh-Dole Act gave PROs the option to elect to own the inventions on the conditions that they would seek patent protection, diligently promote commercial use through licensing, which could be made exclusive, and that the inventors would enjoy a share of the net proceeds in the case of successful exploitation.

The situation in Europe is much more complicated, although certain trends start to emerge.

(1) Several countries or regions have recently enacted laws, regulations or policies assigning ownership or the first right to ownership to PROs. This is the case for Austria, Belgium (with differences between the three regions), Denmark, France, Spain and Russia.

(2) Several countries are holding on the "professor's privilege" system assigning inventions to university professors. This is the case for Finland, Norway and Sweden. Germany had a similar system, which has been abolished recently. In contrast, Italy has gone the other way by enacting a professor's privilege system.

(3) Finally, several other countries have not yet taken a definite policy orientation for technology transfer from PROs.

In the first category, there are variations. Some regulations assign ownership of inventions to PROs and others grant a first right to PROs to elect to take ownership of inventions. In all cases, there is a commitment from the PROs to protect the inventions and to diligently seek commercial exploitation for the benefit of the public, sometimes with preference to national or regional exploitation.

Most of these regulations are imposing a legal obligation on the inventors to disclose inventions to the PRO in order to secure the possibility of protection and development. In practice, this is merely preventing the inventors from filing a patent application on their own or to exploiting inventions to their own personal benefit without first offering the PRO to exploit them for the benefit of the public. Such an obligation is rarely sufficient to induce researchers into investigating the possible economic uses of their discoveries before publishing the results. As we will see later, this is one of the major challenges facing the Innovation Model.

Even in countries that have professor's privilege, most inventors found out that they generally have neither expertise nor resources to file patent applications on their own and find licensees. They have generally assigned their rights to their PRO in exchange for support in the commercialisation process, with any benefits being shared between the PRO and inventors. Regardless of the status of ownership of the IPR, commercial exploitation of new inventions is only ever possible where there is active support by the inventors. In regimes where there is no first ownership with the PRO, the Group considers that arrangements should be set up to enable researchers who own their IPR to have access to a TO, so that effective management of the technology transfer can be ensured

Ownership under Industry Sponsored Agreements

The US Bayh Dole Act provides that the right for PROs to take title to inventions applies to all research funded in whole *or in part* by Federal Funds. Since most collaborative research is making use, at least in part, of background know how, infrastructure and resources from the PRO that are funded by the Federal Government, US PROs generally insist on owning the results of collaborative research funded in part by industry in exchange for granting royalty free non-exclusive license rights. Exclusive licenses are granted in exchange of fair compensation.

In contrast, the common practice in Europe has been for industry partners to insist on receiving full ownership of the research results they sponsor and to retain the first (only) right to file patent applications. Since PROs are supposed to own the research results and discoveries made by their

employees and associates, as discussed above, this means that they would have had to agree by contract to the assignment of such rights to the industry sponsors. Many contracts would also include a provision to the extent that the PRO warrants to be the sole owner of such rights and having the power to assign it to the sponsor, thus creating an onerous obligation for the PRO which may not always have been fully appreciated.

Apart from considerations about fairness and effective collaboration with industry, which are dealt with in Chapter IV, the main problem created by this practice is the management of the intellectual assets.

In this regard, a distinction should be made clearly between ownership of the results and ownership of inventions. The results of a research may have many different forms and have implications on many different fields that are not easily identifiable or protected. The implications may extend beyond the field of interest of the Industry partner. The results from earlier research will become the basis of further research. In effect, the accumulation of results from research truly form the know how of the PRO, which should not be alienated if the PRO is to take an active part in the process of innovation. In contrast, the ownership of an invention and of the patent applications or other forms of IPR protecting it is easily identifiable and does not entail the ownership of the underlying research results. As a matter of fact, the underlying research results fall in the public domain upon publication of the patent application.

The group considers that the good practice is for PROs to retain ownership of the research results, subject to protection of certain confidential information and to granting of certain use rights, and to consider only assigning ownership of inventions to sponsors on fair conditions to be negotiated.

2.3. Joint Ownership

Joint ownership regimes are notorious as difficult to manage. Common wisdom is to avoid creating joint ownership situations at all cost. In practice however, there are many situations where this is unavoidable.

In any form of joint collaboration, it is relatively easy for a party to claim joint ownership to research results and to inventions that may derive from them. There is a risk that parties may overemphasize their own contribution and minimise that of others. It is much more difficult to disprove such claims before civil courts. Therefore it is essential that clear records in the form of signed laboratory books be encouraged in research, which is likely to lead to new technology.

The problems of joint ownership are particularly relevant to PROs for two major reasons:

(1) PROs are more likely to collaborate with many parties at the same time in pursuing research.

(2) Contrary to their industry partners, PROs are generally not-for-profit organisations with neither the authority nor resources to directly exploit their IP by way of sale of products or processes. They can only do so indirectly through the granting of licences.

In Europe, as a general rule, each joint owner may exploit the invention (subject, in some countries, to fair compensation of the other joint owners) but may not assign or license his undivided interest in the invention to other parties without the consent of all the other joint owners. In other words, depending on countries, PROs owning a joint interest in a patent may not grant any licences to other parties without consent. PROs may practice the invention, including in the course of undertaking collaborative research with other partners, but may not grant a licence to the jointly owned background technology that may be needed to exploit the results. Industrial owners, on the other hand, may

directly practice the invention in their product or processes without the consent of any of the joint owners, subject only, in some countries, to a fair compensation of the other owners, including PROs.

By contrast, in the USA, the joint ownership is divided and each joint owner is free to grant non-exclusive licenses on joint inventions to anybody, without accounting to the other parties. Only the granting of exclusive licenses requires the consent of all joint owners. The most diligent party is likely to exploit the benefits. No party can prevent non-exclusive exploitation of joint ownership by other parties, even by PROs.

On the face of it, while European statutes may seem more fair to the joint owners, in reality, they make the management of intellectual assets much more difficult for European PROs, which may be faced with impossible bargaining position in trying to license out some of their IPRs.

In theory, all European statutes have enough flexibility to allow these provisions to be changed by mutual consent of the parties. In practice, these provisions are very difficult to negotiate, even among PRO partners, as was clearly illustrated by the adverse experience in consortium agreements within the 5th Framework Program.

There is no simple solution. The Group proposes the following guidelines:

(1) the exclusive use by one of the joint owner requires the consent of all parties and should be compensated by royalties or other forms of compensation;

(2) each joint owner should be allowed to use directly or indirectly the joint IPR, including the right to grant non-exclusive licences, provided that first options for exclusivity to the industrial co-owners have been honoured;

(3) in the event one of the joint owners obtains significant benefits from the use of the non-exclusive IPRs, the other parties should receive an equitable share of such benefits.

This approach is the one most commonly proposed as the basic position in consortium agreements in EC framework programmes (FP). It is very close the provisions of French IP law. The first point is obvious: it is not appropriate to grant one party exclusive rights without compensation. The second point prevents any party from preventing the grant of licenses, as would be the case for instance under Belgium law applicable to EC FP contracts. The third point is a compensation for the fact that certain joint owners, especially PROs, may not be in a favourable position to exploit the joint inventions.

2.4. Education : Introducing a Culture of Awareness of IPR

If management of research results is to be introduced by implementing the Innovation model alongside the Open Science model, it is essential that there is understanding and acceptance of this mission by the research community. PROs should therefore encourage the distribution of information about IPR and support workshops where interested researchers can find out about what is involved in the technology transfer process. Such meetings can also encourage the exchange of case studies and experiences by other researchers. It is likely that researchers will be keen to support this if they can see that it promotes the development of their research fields.

It is essential that realistic expectations about the aims and success criteria around technology transfer are created as the TO works alongside the inventors. It is important that appropriate incentives are available for the scientists to reward the additional effort they may be required to provide in addition to their teaching and research duties. It is also vital that their academic reputations are enhanced by the traditional publishing activities.

In most cases, the stated policy objectives of the Innovation Model are:

- to increase the likelihood that inventions will be developed and benefit the public;
- to contribute to the regional economic development;
- to make the publicly-funded research function a more attractive pursuit;
- to retain the good scientists;
- to improve career opportunities for the graduates;
- to contribute to research funding.

Some national European laws go as far as making it an obligation for the scientists to disclose to their university the patentable inventions which they might conceive, in the same way as commercial companies do with their own employees.

However, it is neither desirable nor realistic in a PRO environment to try to achieve the goals of technology transfer under a dictatorial regime. The preferred approach is to develop a favourable environment such that there are sufficient motivation and required expertise to support researchers who wish to use the innovation model.

To this end, PRO's and their sponsors are recommended to provide assurance that the objectives of a protection model are pursued as legitimate aims of the research base, consistent with the 'charter' of the PRO. The content of such a charter will be discussed in Chapter (6).

Review of Manuscripts

At least in Research PROs, researchers are trained mainly to discover and understand natural phenomena and are unlikely to be sufficiently sensitised or trained to envision the possible practical applications of their discoveries. In some cases, the conception of an invention would require the meeting of a discovery with the perceived need of practical problems and of the state of the art in the field.

As well as relying on the increased awareness of the researchers to identify new inventions, it is advisable for TOs to arrange for review of certain draft manuscripts in order to catch potentially patentable ideas before they are disclosed. Such review is not proposed for all publications of a PRO, but only those where the researchers, having been made aware of the implications of IPR, may think to offer their papers for review. There may also be certain types of projects where the sponsor or TO may be aware that there is likely to be novel IPR generated and when such a project is being set up, a sympathetic review process could be established. This is particularly the case where strategic relationships with industry exist.

This does require a high level of expertise and it may be a function, which could in the first instance be requested of the researchers themselves, although some TO staff may also have some expertise in the relevant area. In some circumstances where strategic relationships may have been set up with industrial partners, there may be an obligation on the PRO to ensure that novel technologies are notified for patenting to be considered, so strong relationships with the research groups or local patent agents may facilitate this exercise across a broader spectrum of research. Draft manuscripts often form a useful basis for patent applications although often it will be more advantageous for a disclosure to be notified to the TO in advance even of a draft manuscript being prepared.

Invention Disclosures

For technical inventions, the proper drafting and filing of an invention disclosure is a key stage in the innovation management process. This document serves many purposes:

- it formally discloses inventions to PROs as required under several Regulations;

- it enables a preliminary opinion about the opportunity and feasibility of seeking IPR protection, particularly a patent application or a utility model;
- it provides the basis for determining the inventors;
- it provides the information required to assess ownership of the invention in view of the sources of funding and other constraints;
- it identifies possible industrial partners known to the researchers;
- it may constitute a formal date of invention under US patent law, unless a prior date can be established from properly maintained laboratory notebooks[15].

The typical content of an Invention Disclosure Statement is given in ***Table 1.*** This table illustrates most of the issues that need to be covered before a PRO can invest into the filing of a patent application, while minimising the risk to discover later that the invention was not patentable or that ownership does not actually belong to the PRO. Another advantage of extensive invention disclosures as described in ***Table 1*** is to minimise the time spent by patent attorneys on drafting the technical descriptions in patent applications, which is an expensive part of the process.

The proper completion of an invention disclosure is a difficult exercise and may be discouraging for academic inventors. This is why it is a good practice for the TO officer to help the inventors to fill in the declaration and understand the concepts and why they are important. This is also an ideal opportunity for the TO officer to explain to the inventors what they can expect from the TO in terms of diligence in seeking IPR protection (such as filing a patent application) and commercialising the invention. It also enables a frank discussion about what is expected from the inventors if the commercialisation process is to be successful and crucially to have the parties agree on their mutual responsibilities. This is a very important moral contract between the two parties. Unless both parties are committed to and delivering their commitments, the time and money spent on patent applications is surely wasted.

Having identified a potential disclosure, it is now necessary for the KTO to carry out due diligence to see where the ownership and management rights may lie.

2.5. Centralise Responsibilities for Management of IPR

Despite the range of legal regimes regarding ownership of research results and inventions, if there is to be effective technology transfer in accordance with the mission of the PRO, then initial exploitation responsibility should rest with the TO.

The model, which is emerging as best practice for public sponsored research at PROs, is as follows:

(1) Assign ownership of ***research results*** to PROs;
(2) Oblige/encourage inventors to disclose to the PRO the ***inventions*** based on the research results before publication;
(3) Give the PROs the option to elect title to the ***inventions***, in exchange of the commitment to diligently protect and commercialise the inventions for the benefit of the public. As an alternative, the PROs may license or assign such rights to industry partners;
(4) Share the net proceeds, if any, from such commercialisation with the inventors (and their groups);
(5) Should the PRO elect not to take title or fail to diligently exploit the inventions, title would revert to the inventors.

This approach is now widely accepted[16] and should be implemented across the European Research Area.

[15] see e.g. http://www.btgplc.com/btguploads/BTG_LabNotebook_Jul02.pdf

2.6. Professional Management of the IPR Portfolio

Management of patents and other IPR is the cornerstone of PRO technology transfer. The purpose of this report in not to discuss in details the key issues attached to each form of IP. Detailed guidance and an in-depth overview can better be gained from referring to any of the specialist texts detailed in the bibliography or by consultation with professional advisers.
The nature of research activity inevitably means that research results will be subject to a wide range of IP rights. This includes automatic rights as well as those that require formal registration in order to exist. For exploitation purposes, the types of Intellectual Property of greatest relevance to PROs are patents, copyright and know-how/confidential information. A PRO must understand what IPR is in order to identify which skills and resources ought to be available to the PRO if effective IPR management is to be cultivated. For further information and an introduction to IPR in the PRO environment, see for instance the AURIL Handbook.

Intellectual Property Protection

Since some rights require a formal process, there are resource implications for a KTO. The financial aspect is one that needs to be carefully addressed, particularly for the patent process. IPRs are a means to an end i.e. one of the necessary elements of the technology transfer package and need to be managed effectively. KTOs need to have access to resources to underwrite at least the early life of the above rights. Costs will be associated with external professional advisors (such as patent agents) as well as official fees due to the national agencies.

Realistic budgets need to be set for the KTO to be empowered to manage IPRs. In certain countries there is access to public funding to support IPR costs and is an eligible cost under European FP6.

It should be observed that patents are especially important for PROs for several reasons:

(1) They are the only way to reconcile the mission to disseminate knowledge through publications with that of protecting the investments in the development of useful applications;

(2) In contrast to patents filed by industry, patents filed by PROs are more strategic in nature, i.e. to encourage development, than tactical, i.e. to limit competition.

(3) The ownership of patents can be instrumental in attracting collaboration with industry;

(4) The granted claims are an objective basis for assessing royalties and other forms of compensation and of distributing the process to the inventors and their research units.

On the other hand, non-registerable rights are assets in the same way as the registered rights. However, despite being apparently more attractive because of the absence of formal registration fees, they can be more difficult to manage and identify, since demonstrating originality and ownership is complex in a PRO environment. Again, it is essential that KTO personnel have an understanding of the parameters of such IPRs in order to identify the correct portfolio of technology for an exploitation opportunity.

[16] See for instance the conclusions of the workshop held in Brussels on February 15, 2001(several official report refs are possible also)

Respect for Third Party IPR

It is essential that, having become aware of its own IPR, the PRO ensures that wherever possible it accords respect for the IPR of other parties. In general, because PROs are not-for-profit organisations, it is rare for patent infringement or other problematic events to affect them. But as PROs become more involved in licensing and engaging in collaborations with industry, there may be an increase in the situations where a PRO is seen to be a threat to the IPR of a third party.

Research Exemption

While carrying out due diligence into research in a PRO, it is important that TOs are aware of the relationship between certain IPRs and research practice. A political storm has been brewing for several years around the impact of certain biotechnology patents and freedom to carry out research. Examples can be seen when we look at the PCR and Cre-lox technologies where licences for their use in research environments is required.

In most countries of the world, patent statutes exempt certain acts from being seen as infringement of valid patents. To what extent are PROs protected from infringement proceedings in the course of conducting research?

In the USA the research exemption persists but in very narrow form. The Court of Appeals for the Federal Circuit has held that is limited to acts done " for amusement, to satisfy idle curiosity or for strict philosophical enquiry" and that it does not apply if the act has the slightest commercial implication. Therefore the research exemption may not extend to research with no commercial application but which may be seen to further a university's legitimate business objectives, for example by increasing the status of the university and thereby luring research grants, students and faculty to it. The Supreme Court refused to interfere with this judgement.

In the UK the research exemption applies to acts " done for experimental purposes relating to the subject matter of the invention, it being irrelevant whether the act is done for commercial purposes or not. One view therefore is that in the UK the use of the patented research tools will require a licence while research into the tools themselves will fall under the exemption. A similar interpretation of UK legislation applies. However there is a European school of thought that clearly supports the notion that if the use of the tools is for non-profit-making purposes, then the exemption should apply.

The pragmatic position for PROs to take is to be aware of the existence of third party patents and find out what approach the owner is taking. In certain circumstances research sponsor may wield some authority to persuade patent owners not to render the cost of undertaking research too high by insisting upon licences.

Material Transfer Agreements

As well as information as described above, it may be that there are quantities of tangible research materials that a PRO has developed and currently holds. Although all the methodology for replication and production may be published, it may be that third parties wish to access the particular supply held by the PRO. Industry also makes such materials available for research purposes, usually under material transfer terms. Although there may no formal IPR position in terms of any of the rights described here, there are frequently licence type arrangements entered into governing the supply of this type of material. In such agreements, care needs to be taken to address the situation where future IPR may arise as a result of use of the materials and parties should be pragmatic about what terms ought to be reasonable. There has been much debate about material transfer agreements and for an example; reference is made to the Uniform Biological Material Transfer Agreement, which is the result of many years negotiation in the USA between the National Institutes of Health and industry. (See AUTM manual)

Parties should hope to see terms and conditions similar to those that they include in their own MTA for outgoing Material. Issues that are often problematic concern publication rights, ownership of research results and their commercial exploitation. The MTA should allow publication of research results and retention of ownership of research results by the researching party. If a commercially valuable product were developed with the transferred Materials it would be appropriate to negotiate access to transferred Material in order to exploit our developments whilst recognising the contribution of the original supplier.

Confidential Information

It is important to ensure that, where industry shares its proprietary information with researchers, it is securely managed. Without confidence that this can be done, companies are going to be nervous of entering into relationships with PROs.

2.7. Harmonisation of Legal Regimes and other international issues

Patents and Innovation[17]

Registered rights such as patents and design rights are among the most complex to acquire and the national nature of the geographical rights obtained have a huge impact on the efficacy of the technology transfer process. Costs are escalated due to the need to have several translations of the relevant documents, timescales for the start and conclusion of rights vary and the very nature of the granted right may also vary substantively depending upon the final determination of each national office. Across the EU therefore it has long been recognised that to have a single patent and common copyright regime for all members would be ideal. As with all other harmonisation activities this is a time -consuming and costly process, which is why even today there is no single Community Patent and as yet the law of copyright has so far only achieved concurrence around the duration of copyright. There is no single utility model or design right, but steps are being taken to move these forward. In order to ensure that there is increased efficiency in dealing with technology transfer, it is essential that there be some harmonisation of the diverse regimes governing IPR. A summary of the current situation and recommendations is found in the OECD report.

International Research Collaborations

There has been work carried out by another Expert Group[18] on these issues, whose findings may be useful to PROs.

Competition Law (Antitrust) Issues

Originally there was even some debate about whether IPRs could continue to exist on a national level, since their very existence depends upon national boundaries. However, early case law of the European Court of Justice demonstrated that only the *use* to which such IPRs were put could be challenged by the competition rules. Exemptions have been granted in advance to whole categories of agreement (art. 81§3 allows block exemptions) and for those involved in technology transfer and collaborative research and development agreements.

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[17] OECD *Patents and Innovation in the International Context* OCDE/GD (97) 210, 1997 – http://www.oecd.org/dataoecd/35/13/2101372.pdf

[18] EC Expert Group Report on *Role and Strategic Use of IPR in International Research Collaborations* EUR 20230, 2002 – http://europa.eu.int/comm/research/era/pdf/ipr-eur-20230_en.pdf

For PRO's and their industrial partners, it is important that due consideration is given to arrangements entered into in order to ensure that no infringement of competition rules occurs. Technology transfer agreements must comply with EU competition law and in particular with Regulation 240/96. Advice from those skilled in the detail of this discipline is recommended.

Arbitration

The use of Alternative Dispute Resolution clauses to handle all disputes (e.g., Med-Arb, WIPO) should be seriously considered in some cases or else face the consequences of inconsistent court decisions and territorially limited national regimes.

2.8. Conclusions

For the PRO creating, owning and managing a portfolio of IPR, whether registered or unregistered, is an expensive exercise. Given the costs of certain IPRs such as patents, it is essential therefore that a good business case exists to justify maintaining these IPRs in each country where it was initially filed for.

It may be easier for industrial partners (whether large industry or start-ups) to litigate or license our IPRs in a business context, especially where a PRO may have non-for profit status, and is not willing to become involved in enforcement procedures or multi-jurisdictional litigation. On the other hand an industrial partner will need to satisfy itself that the IPR protecting the relevant invention is valid, enforceable and of adequate scope. Concerns on any of these issues will be a serious deterrent for an industrial partner.

For new companies whose early stage assets are likely to comprise entirely of the IPR portfolio that it will own or have rights to, the cost implications are a considerable element of their early stage funding and needs to be properly understood and budgeted for.

The substance of any exploitation deal between a PRO and an industrial partner will comprise a bundle of different types of IPRs and may raise complex issues of intellectual property law or competition law. The results of a project will always contain copyright material and is likely to contain patentable subject matter, confidential information/know-how and tangible materials (e.g., materials or prototypes). In essence the transfer is an opportunity to develop the technology further rather than an end product therefore it is essential that the relevant IPRs are properly created, identified and managed so that they can be attractive to industry or start-ups.

PROs should also consider whether it is appropriate for them to retain access to or control of the IPRs. In some cases it may be best to assign all IPRs outright to a buyer or start-up company in exchange for equity. In some other cases it may be preferable to grant only licenses, on a non-exclusive basis or limited exclusivity basis, so that the PRO and others can continue to use certain aspects and ensure ongoing development of the technology. KTO personnel need to be in a position to understand the needs of the industrial sector in each area and to be flexible in the form and degree of transfer as a result. It is essential therefore that a good dialogue takes place with the commercial partners or entrepreneurs to ensure that effective and appropriate management of the IPR be maintained.

Pooling of PR may also be an effective way to ensure development of complementary technologies. Through effective networking this can be done across different organisations. PROs should be careful to avoid being too protective of their own IPR at the expense of collaborative opportunities. Provided transparent and realistic discussions take place it should be possible for exploitation of joint portfolios to be successful.

Table 1: Invention Disclosure

	Title	Content	Comments
1.	Serial Number	Assigned by TO upon acceptance	
2.	Title		
3.	Summary description	Short description in general terms	
4.	State of the Art	List of publications known to the inventors or which have been discovered from patent searches by the inventors and considered relevant	Legal obligation under US patent law Important to assess patentability
5.	Problem solved by the invention	Description of the advantages conferred by the invention over the prior art and possible applications	Important to evaluate the market potential and the patentability
6.	Detailed Description of the Invention	Description of the invention and of the state of development in sufficient detail for a person skilled in the art to understand the nature of the invention	Essential to give a date on the invention and asses patentability. Items 4, 5 and 6 facilitate the drafting by a patent attorney.
7.	Inventors	Complete identification of each inventor, including Name, business and private address, position, employer	Necessary to complete patent applications
8.	Contributions to the invention	Description by each alleged inventor of his/her contribution to the invention, identifying inventive activity and reduction to practice	Can be used as the basis to determine inventors by a patent attorney. Description is meant to be seen by all inventors in order to minimise the risk of ungrounded statements
9.	Funding	Description of the funding used to fund the research leading to the invention, with copy of the research agreements	Necessary to verify conditions of ownership and possible covenants on exploitation
10.	Collaborations	Description of all external contributions to the research and to the invention, whether compensated or not, with copy of the relevant agreements when they exist.	Required to verify cases of possible claims for joint ownership.
11.	Confidentiality	Declaration concerning possible incorporation of information obtained from 3rd parties under confidentiality agreements. Copies of NDA.	Verify right to incorporate such information and need for consent
12.	Use of materials	Statement concerning possible use of materials supplied by other parties. Copies of all Material Transfer Agreements, if any.	Check on possible claims on ownership or license on the invention or rights of first refusal.
13.	Publications	Checklist of all possible disclosures that may have been made by inventors with date and copy of information disclosed (Articles, Abstracts, Proceedings, Doctoral Thesis, Internet, posters, etc)	Verify possible bar from patenting on novelty or obviousness because of communications by the authors themselves. May restrict patenting to certain countries
14.	Possible licensees	Identify the companies known to the inventors that may be interested in taking a license or doing collaborative research	Facilitate the search for industry partners and the assessment of market potential.
15.	Signatures	All inventors sign the invention disclosure and confirm their agreement on the applicable university regulations concerning ownership and commercialisation. They commit to collaborate actively to the filing of the patent application and in the search of licensees. For inventors which are not covered by the regulations, attach the agreement assigning their rights to the University	Incorporates in the document the basis of ownership and management of the IP rights.
16.	Witnesses	Signature of 2 witnesses skilled in the art, who declare that they have read the document and understand the invention on that basis alone.	Constitutes proof that the invention had been conceived on or before that date.

3. CHAPTER THREE

Technology Transfer by Licence Agreement

This chapter explores some of the issues around licensing of technology from a PRO into a traditional industrial environment, while a later chapter will look specifically at licensing technology into spinout companies.

Key Messages

Licensing is an effective method of ensuring that commercial development and exploitation of technology can be undertaken by industry for the benefit of society.

There are certain circumstances where assignment of patent rights to industry/third parties is necessary.

Care should be taken to clearly identify the subject matter and extent of rights in the licence.

Valuation of IPR should be realistic- neither side should seek to be greedy!

A licence is a relationship, which needs to be nurtured so communication throughout the life of a licence is crucial.

3.1. Background

This form of technology transfer is more widespread in the USA than in Europe. The license revenues of an average US university technology transfer office is typically a factor 10 larger than that of the European counterpart and is one of the key indicators of the metrics used by AUTM for measuring the effectiveness of technology transfer. The following table compares the average licence income to US, Canadian and UK PROs:

Indicator	USA	CANADA	U.K.
Number of PROs responding to the survey	141	19	72
Number of licences yielding income	7,562	453	483
Amount of research expenditure per income yielding licence	3.6 M Euros	2.9 M Euros	4.3 M Euros
Amount of licence income earned for each Euro spent on research expenditure	4%	2%	1%

Source: UNICO-NUBS survey FY2001

It is observed that the number of licences yielding revenues and the licence revenues are much larger in the US and, to a lesser extent, in Canada than in the UK. If the comparison had been extended to the whole Europe, the difference would have been even more dramatic.

The difference is attributed to the combination of several factors:

- Most European PROs have a relatively low number of patents compared to their US counterparts, not because the science in the US is better, but because of a larger propensity to file patent applications. In addition, the US patent system is reportedly 5 times less expensive than the patent system in Europe.

- There is also a time lag effect, since the US PROs have been encouraged to patent since the passage of the Bayh-Dole Act whereas the interest for European PROs to manage their IP is only recently starting to spread;

- The demand for licenses from PROs is also larger from US companies than from European companies because of a larger domestic market and a more active network of technological SMEs backed by venture capital. Indeed the problem facing us could even be described as being a surfeit of potentially great new technologies, which because they come from PROs are too early to warrant industrial investment. The recently published Lambert Report from the UK[19] indicates one other reason for the lack of industrial uptake, namely the dearth of technology-dependant (research- active) industries in Europe. For those that are around, very often the risks are just too high.

- The funding of PRO research by US government is significantly larger than in Europe, both in absolute terms and in relative terms, with the US government funding more than 90% of all PRO research.

Therefore we need to find ways of getting more development funding in order to weed out technologies that truly have no commercial application, thus ensuring that if the proof of principle does work there is a greater likelihood of an industrial partner running with the development. This call for a more strategic relationship with not just traditional industry (see chapter 4 below) but with other stakeholders, such as local economic development agencies and VCs (see chapter 5 below).

3.2. General Principles of PRO licensing

Technology Transfer from PROs into the industrial environment has traditionally adopted a licensing model. The PRO grants user rights to its intellectual property in the form of a licence, which can be exclusive, with or without the right to sublicense, which enables the industrial partner to develop and commercialise covered products and/or processes in return for licence fees and/or royalty income related to the commercial returns achieved by the industrial partner. There are a number of reasons from the PRO perspective why this is a desirable model.

Firstly there is no sustained dilution of the Intellectual Property Rights including know-how and methodology which reflect the vast expertise developed and acquired by the PRO Research Departments over many years, supported by a broad range of research sponsors.

Where new technology is identified then PROs are obliged to ensure that appropriate development and downstream use can be made of the early stage technology rather than it sitting locked away in a university laboratory or alternatively perhaps being sold or licensed to a company, which does not proactively develop or make use of the technology. Therefore, by entering into a License Agreement, the University establishes a direct partnership with the industrial partner, which means that there can be a dialogue about the use of the technology and its potential as a commercial product or process. In

[19] "Lambert Review of business-university collaboration" – http://www.hm-treasury.gov.uk/media//06729/lambertemergingissues_173.pdf

other words, from the PRO perspective, technology should be given the best possible chance and if it fails to be a commercial or useful product then it should be as a result of the technology itself failing or because there is better or more efficient technology available to the industrial partners. It should not fail because of a lack of effort by either the PRO or the industrial partners.

Another key aspect of the licensing model is that very often technology from PROs is of a generic nature and therefore there will be a wide range of potential users in different technical fields. By granting licenses to a wide range of industrial partners, then the technology can be developed and used in each of the relevant fields.

From the industrial perspective, the licensing model has also been shown to be an attractive one and works very well for many different industries. The key to the discussion about the licensing model is that both sides need to separate issues of ownership from issues of user rights. Although ownership of the intellectual property rights may vest in a single party such as the PRO, if the industrial partners have sufficiently clearly defined user rights to make commercial gain from the technology then the model can be a win-win solution for both sides. In particular, where licenses are granted on an exclusive basis, companies are fully enabled to acquire the rights they need to both use the technology and also to protect their user rights against third party infringes (provided that the licences are registered).

3.3. Market Models

There can be two approaches to identifying licensees:

1. Active licensing by promoting the technology and offering licenses to potentially interested commercial partners well positioned to develop and use the technology;

2. Compliance licensing by searching out likely infringers of the patented technology and negotiating licence revenues in exchange for freedom of exploitation.

There are a number of organisations and publications that provide very useful information for both licensees and licensors. Information available in the public domain includes details of typical deals for example in the Biotech or Pharmaceutical Industry along with extensive information collated by US PROs in connection with trends in licensing revenue and licensing activity.

3.4. Key Issues to be addressed in the Licensing Agreement

As with any other contract, the content of a License Agreement is a matter to be freely negotiated by the parties involved. These guidelines are intended to provide only a general overview and a KTO should ensure that it has access to appropriate professional advisers. However, there are certain issues, which the Group feels ought to be clearly agreed upon by the parties and addressed in the written agreement in order to ensure that the licensing partnership succeeds.

3.4.1. Carefully define the subject matter of the License

Because there are a wide range of intellectual property rights such as patents and copyright through to confidential know how and tangible materials such as animal models, it is very important that everybody is clear about the subject matter of the licence. It is possible to define different access rights to different types of Intellectual Property in a single licence agreement and it should be

remembered that it is likely that a range of IPRs will be required by the industrial party, including patent rights, materials and Know-how.

3.4.2. Scope of the License

This is the key aspect of any License Agreement. Decisions need to be made about the scope of the rights to be granted. Are they to be exclusive? Non-exclusive? A combination? Exclusivity can be granted to the whole IPR portfolio, or simply to certain parts e.g. Patent Rights, while other aspects remain non-exclusively licensed such as know how and methodology. Exclusivity can also be defined by different fields of use e.g. for use in the chemical industry while the same technology could be exclusively used in the electronics industry where the two fields of use are not competitive. Furthermore, territorial exclusivity is also a potential model e.g. the North American market could be licensed to a different company from that which operates in Europe.

Depending on the nature of the technology, it may be attractive for industry to acquire non-exclusive rights. This is often the case where either the technology is at a very early stage such that the end product or process, which would generate commercial income, would be the subject of independent Intellectual Property Rights developed and owned downstream by the company. Alternatively where the technology is of a truly generic interest where there may be other alternatives available such as alternative software models, any non-exclusive user license may be attractive.

3.4.3. Sub Licensing

In determining the scope of the license rights to be granted, as well as the direct rights by a company to commercially develop, market, sell, utilise etc., the access by third parties to technology ought to also be considered. Depending on the nature of the technology being licensed, it may be necessary for the main company licensee to be able to pass on i.e. sub license some of the rights to third parties e.g. customers or partners. Alternatively, the PRO may not wish the licensee company to sub license all rights to third parties in place of a direct license being granted to a third party by the PRO. These matters ought to be clearly agreed upon by the PRO and company.

3.4.4. Performance Obligations

In granting licences to technology, it is important to ensure that the company assumes obligations to develop and utilise the technology until either it reaches the market or otherwise fails to fulfil its commercial promise. It is important for the PRO to see that the technology is not locked away, so failure by a licensee to fulfil this obligation should lead to a reduction or loss of rights.

3.4.5. Reward Mechanisms

While granting licenses to allow technology to be developed and to commercialise can be seen as a speculative process because of the nature of PRO technology is usually at such an early stage, the parties must also be reminded that the technology may in fact turn out to be highly successful. A balance needs to be found to reflect the relative contribution of the PRO and the company to the commercial success. While the early stage development will have been done by the PRO, there may be an early stage upfront payment for the PRO in return for granting a license. However, other factors will determine the ultimate “price” of any license to be entered into. The stage of development of the technology, the nature of the technology and the scope of the rights being granted to the industrial partner will all determine the level of reward to the PRO. It is normal for there to be some element of an upfront fee (unless the industrial partner has been collaborating to sponsor the early stage research) however, other financial aspects of the license usually link the success of the technology to an entitlement to revenue sharing. It is common for a series of milestones linked to the development of the technology to perhaps trigger further payments to the PRO. Ultimately, if there is commercial success then a royalty payment linked to the level of commercial success is usually acceptable to all parties. In this way, where the industrial partner is bearing the risk of all the downstream development,

it is not usually required to pay additional licensing fees unless the technology turns out to be successful.

3.4.6. Patent Management

If the subject matter of the IPR includes patent portfolio then it is important for the parties to agree exactly where responsibilities will lie. Issues include decision making about the prosecution towards grant of the portfolio, allocation of responsibility of meeting the costs of such prosecution. In addition, responsibility for pursuing infringers or being entitled to defend infringement allegations needs to be agreed.

3.4.7. Termination of License

Obviously to be comfortable that the license rights held by the company are sufficiently robust to justify substantial development by the company in the technology, there must be very limited grounds for the license to be terminated. There is likely to be a relationship between any performance obligations, which the company has undertaken with regard to actively developing the technology. The PRO should only be entitled to terminate any license if there has been a material breach of the provisions of the agreement, including where the expectation that the company proactively develops technology has not been met. Careful discussion between the parties about the different triggers for any such termination needs to be set out. Linked to this issue may be an option to identify an external arbiter whose opinion about the compliance by either party with the terms of the license may be helpful.

3.4.8. Indemnity/Liability

While the company will require some satisfaction that the PRO is entitled to enter into a License Agreement, there may be warranties requested about ownership of the relevant IPR etc. However, there may be a downstream exposure to the PRO to claims by third parties who may have suffered loss as a result of using the technology made available by the licensee company. It is usual for there to be at least product indemnity offered by the company to the PRO. However, downstream responsibilities to third parties need to be agreed carefully between parties. Different legal jurisdictions have different expectations of the retained responsibility of any owner of IPR. For example in the United States there can be reach through by claims to the patent owner notwithstanding the fact that the license may pass on responsibility to a licensee company.

4. CHAPTER FOUR

Key Aspects of Interaction between PRO's and Industry

Part of the traditional role of PROs has long involved interaction with industry. The nature of these interactions is diverse and in particular there has been a long culture of collaborations where specific research results have been transferred from the PRO to the control of an industrial sponsor or co-sponsor in return for a contribution towards the costs of a portion of the research work. The scope and possible limitations in the context of effective technology transfer are explored in this section. A new era of more collaborative relationships between PROs and industry is also emerging and provides evidence that the Innovation Model can be an effective one.

Key Messages

Direct and frequent interaction with Industry remains the most effective way for PROs to contribute to Innovation.

The innovation model will enable the existing wide range of relationships between industry and PRO to develop into more useful and productive collaborations.

The burden of identifying and developing early stage technologies cannot be borne by industry alone.

The goal of developing a knowledge economy by increasing R&D cannot be achieved without a stronger interaction between Science and Industry.

Unless the Innovation Model is implemented, novel technologies will continue to be lost to society.

The respective aims of the private and PRO sectors can work in harmony. A charter of collaboration outlining certain principles would be a helpful tool in this process.

Background

There are many different relationships that involve interaction between an industrial company and a PRO including research collaborations, service-type collaborations, technology transfer arrangements – including licensing or selling intellectual property rights - as well as multi-party consortia such as those established within EC Framework Programs. Indeed, as the Framework research programmes have evolved, there has been an increasing trend in the desire and obligation of partners to enter into formal consortium agreements.

4.1. Trends in PRO-Industry research collaboration in Europe

Often such collaborations were governed under the Open Science Model where PROs were not interested in retaining ownership and use rights of some of the results. The main incentive for the PROs to engage in industrial collaboration was the ability to carry out further research using the financial contribution to sustain the research team in order to publish results of scientific significance.

The industrial partners were generally happy with this approach to the extent they could acquire and own, often at a fraction of the cost, valuable technologies, which they could exploit to their advantage. In fairness, most PROs were also happy with this model, which does not require them to get involved in the management of their intellectual property.

The main disadvantages of this model are that it neither rewards the investment of public sponsored research nor does it ensure that potentially useful new technologies are transferred to an environment that is able to fully develop and commercialise them. In effect, the open science model does not allow the progressive build-up of a technology pool for the PROs, which can be made available to develop more collaboration, create spinout companies or grant licences. Since industrial partners often select a particular PRO for research collaboration due to the existence of the PRO's background IP and expertise in a particular discipline, then, unless a PRO actively manages its IPRs, many future opportunities for research and development may be lost.

The state of collaboration between PROs and Industry and the role of framework conditions has been investigated under a large Research Project sponsored by the EC and the Austrian Ministry of Economy and Labour[20]. The report concludes that lower levels of Industry-Science Relations (ISR) can be attributed mainly to a lack in demand on the enterprise side.

Three major trends have started to reshape the relationship between PROs and industry:

(1) Public research sponsors, local governments and the European Community now demand that public sponsored research be used effectively as a competitive tool to promote economic development.

(2) Science is moving faster than ever before and the economic applications increasingly involve the combination of several disciplines. At the same time, industry is concentrating on short-term return objectives and core business. There is a definite trend to separate basic research, mostly public sponsored, performed by PROs from development, mostly industry sponsored, performed mainly by industry. PROs and Industry are thus becoming more complementary and the more successful companies tend to outsource a significant part of their research to well selected PROs.

(3) The goal of increasing the levels of European investment in research can only happen if there is greater collaboration between industry and PROs.[21]

In order to co-operate effectively, PROs and industry must recognise one another's constraints and missions. Industry partners are in business to maximise shareholder value. PROs, in addition to their teaching and research missions, have now received a new mission to maximise the social and economic returns of their research results to the public.

Industrial perspective shows that researchers often do not appreciate or understand the full development processes required to take early stage technology to an end product stage. KTOs can do more to increase this awareness and also take care not to over-value intellectual property rights, which makes it difficult for industry to access them. The position with regard to awareness of the development process and understanding true value of IPR are questions which challenge both the technology transfer offices and industry who share a mutual obligation to assist one another in increasing awareness about these issues.

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[20] Benchmarking Industry-Science Relations - The Role of the Framework Conditions - June 2001, http://www.benchmarking-in-europe.com/eu_initiatives/enterprise_dg/framework_conditions/isr.htm

[21] This is one of the conclusions of the European Research Advisory Board document on "Improving innovation" published under the reference EURAB 02.053 final – http://europa.eu.int/comm/research/eurab/pdf/recommendations2.pdf

Is it possible to reconcile these objectives and increase the total effectiveness of the technology transfer function of PROs? The Group firmly believes that this is indeed the case, provided that certain guidelines are adhered to by both parties and ideally embodied in the collaborative research agreements to be executed before commencing the research.

4.2. Towards the Innovation Model

Closer interaction with industry can enable early technology opportunities to be identified and for the partners to lever additional development funding. More dialogue means greater understanding of one another's skills and needs. There is a range of recognised interactions, more fully defined in a report by the Confederation of British Industry[22] and covers: Contract research; Collaborative research: Sponsored research; Other research links associated with third party funding; Postgraduate studentships; Student projects and placements; Sponsored and honorary posts and secondment; University consultancy and associated commercial services; Clubs and networks.

However, it is essential that the parties understand the implications of the research-related relationships they enter into. If there is to be proactive management of new inventions from PROs then collaborators need to have open communication about the management strategy to be employed. It is time to be transparent about all the terms of engagement. Negotiations can proceed via different media, but it is essential that a relationship develop among those involved. Parties should remember that they are in the process of establishing a relationship which may well not only continue for several years, but develop to cover other projects and different scientists. Therefore this long-term aspect of the relationship should encourage parties to negotiate terms that all parties are happy to accommodate. If negotiations are conducted in a professional manner, then mutual respect and trust will more quickly be established, thus providing a solid foundation for the overall relationship. Few problems cannot be solved if communication doors remain open.

For the purposes of recognising the issues that need to address a change in practice from using only the Open Science Model to one that promotes adoption of the Innovation Model, it is useful to distinguish between two main types of research collaboration:

1. **Contract Research** where the PRO is being paid to apply existing knowledge and expertise to a particular situation rather than developing new solutions or new ideas. No significant contribution to science is to be expected. This tends to arise in projects aiming at improving technology that already exists. Industry prefers to interact with PROs acting as service providers with expertise and/or specialist equipment.

2. **Collaborative Research** (including sponsored research as defined in the CBI report), where there is a true collaboration and significant intellectual input is provided by the PRO. This type of research is expected to contribute to science. The intellectual expertise of the PRO is being sought to identify novel solutions or explore new territory and industrial partners are keen to financially support the efforts of the PRO. This can be called 'novel research', where there is a true collaboration such that intellectual input is being developed by the academic base. There are many examples of industry/PRO collaborations of this nature, and in certain scientific disciplines, such as life science research, the industrial partners rely greatly on the research base of PROs for access to new ideas and early stage technology.

[22] CBI Partnerships for Research and Innovation between industry and PROs, CBI Publications, ISBN:0 85201 553 6

The following section highlights the key issues where negotiation and agreement need to be reached in order to distinguish between traditional contract research and more collaborative links, which will ultimately promote effective implementation of the Innovation Model[23].

4.3. Practical Guidance Covering Key Aspects of a Research Relationship

The partners in each of the above relationships need to reach agreement if the objectives of both parties are to be met. These include questions of access to background intellectual property rights as well as determining ownership of downstream results and user rights.

Define the nature of the relationship to be entered into between industry and academia.

It is essential that all parties to new relationship understand the objectives of the collaboration, and it will be very important for each party to understand the issues and perspectives of the other(s). In this way a deal ought to be able to be constructed which best reflect the common aims. Is the collaboration intended to be sponsored research, collaborative research or contract research?

Ownership of research results and inventions

In most European countries, especially southern Europe, we are still facing the general custom that the one who sponsors the PRO research frequently owns the results, without due consideration for the use of the accumulated background technology and for the government funded infrastructure. Since most of the research performed in PROs is either government or industry sponsored, the PROs end up owning virtually nothing. Most European countries have now addressed this problem for government sponsored research by providing either legislation or assigning ownership to the PROs. The challenge remains for research sponsored in part by industry to be made available to the industrial partners since their role is to take potentially useful results and convert them into economic and societal benefits.

Where the PRO does not retain any ownership of IP, this is not only counterproductive in terms of motivation of the academic staff, but also means that effective management of new technology is becoming almost impossible. Indeed, as the university keeps building upon the results of previous work, it becomes impossible to keep track of who funded what. There is always the risk that ownership will be challenged later and this will discourage most potential licensees.

The same issues arise when corporate funding of research is involved. It can sometimes be much more difficult to convince industry that leaving ownership with the PRO and obtaining license rights (exclusive or non-exclusive) is an efficient and effective model for all concerned. However, it is now becoming more understood and accepted by some industrial partners that because the results of a research project may have wider applications than sought by such partners and because they can serve as the basis to further licensable developments, then industrial needs can be accommodated by way of licence rights.

The right to retain ownership by the PRO carries certain obligations:

1. To ensure that their ownership rights are not jeopardised by inadequate IP management. In particular, when the research involves associates which are not bound to the PRO by employment agreements, such as students or researchers paid by grants, to ensure that these associates have assigned their intellectual property rights gained through the

[23] For a discussion of some of these issues, see also the report assembled by the Business-Higher Education Forum: *Working Together, Creating Knowledge: The University-Industry Research Collaboration Initiative*, http://www.acenet.edu/bookstore/pdf/working-together.pdf

collaborative research to the PRO, generally in exchange of becoming eligible under the profit sharing agreements, if any.

2. To safeguard the confidential information obtained from the industry partner and the intellectual property generated by the collaborative research (Foreground IP) by adequate means, including non-disclosure and the filing of patent applications when warranted by the potential economic uses.

3. To ensure appropriate utilisation of the Research Results, including obtaining adequate diligence commitments from the Partner on the development of the uses licensed to him.

Even when the collaborative agreement assigns ownership of certain IP to the industry Partner, the IP must first have vested with the PRO before it becomes assignable.

The general policy to keep ownership of all the results generated in the university and to grant commercial licenses, is fairer, more manageable and more efficient in terms of socio-economic benefits.

Assignment of ownership

In practice, user rights in the form of a registered exclusive license can be equivalent to owning the corresponding IP for commercial purposes. There are, however, certain instances where the industrial partner may still prefer to be the owner of the IP, such as:

- to facilitate mergers and funding by venture capital.
- to avoid depending on the performance of the PRO to maintain the patent rights;
- to facilitate enforcement without going to the burden of registering the licences in all the covered countries;

In those cases and provided that the concerns are justified, some PROs may agree to assign ownership of all or part of the research results and associated IP, provided that the assignment is accompanied by the following commitments;

- financial compensation, particularly if the technology is successful;
- the grant back of a non-exclusive royalty free licence, with right to sub-licence, to the PRO for all uses other than those exclusively reserved to the Partner; and
- undertakings by the industrial partner to diligently develop the IP.
- Re-assignment back to the PRO in case the Partner fails to develop the IP.

Joint ownership

Even though general wisdom is to avoid joint ownership, there are many circumstances in all forms of collaborative research where joint ownership is unavoidable, unless allocated under strict rules agreed before starting the research.

The potential problems have been outlined in chapter 2 above but the fact remains that it will not be changed easily in each national law and there is no other choice than adapt the IPR management policies to this reality. Fortunately, there is nothing to prevent the parties from agreeing to distribute among themselves the ownership and the licensing rights of the results. This should be done preferably before commencing the research. The best approach and the easiest to manage would be:

- First of all, one should distinguish between results and inventions. As advocated earlier, the ownership of the results should remain vested in the PRO having generated them,

except perhaps those results which are specific to confidential information provided by the industry partner and which are covered by confidentiality.

- To allocate ownership of the jointly generated IPRs to the extent possible according to predefined criteria corresponding to their nature. The most common criteria are to location where the research was conducted or the field of application.
- To agree that, for the joint IPRs not meeting such criteria, the joint property is divided and each party is free to use them non-exclusively, including the right to grant non-exclusive licences;
- To include arrangements about which party will have responsibility for pursuing infringers.

Access rights to PRO background technology

The existence of background technology is often the most important consideration for an industrial partner in selecting a particular PRO for collaborative research. The partner needs access to the background technology of the PRO to the extent required to make commercial use of the results. Such background IPR must be identified, including patents, copyright and more generic information such as Know-How, materials and animal models. It should also be noted that the PRO can rarely grant exclusive licenses to such background IPR, unless perhaps in narrowly defined fields of use.

There is a balance of interests to be achieved: the access right is equivalent to a commitment not to sue the Partner for unauthorised use of the background IP in the process of using the foreground IP. However, when the background IPR of the PRO has commercial value and/or is protected by patents, financial compensation for the opportunity loss of not being able to grant exclusive licenses to other parties may be justified and should be negotiated explicitly in the research agreement before commencing the research.

Patent prosecution, maintenance and enforcement of patent rights

Whoever owns the IPRs, the agreement should provide that IP generated from the collaborative work should be managed effectively in order to maximise the chances of economic use.

The decision to apply for patent protection should also be covered by detailed procedures. Historically, PROs did not have sufficient expertise to manage patent applications and this responsibility was attributed to the industrial partner, under contract research arrangements. Today, many PROs have developed such capability as an integral part of their IP management responsibility and are able to take initial steps to protect their registerable IPRs that have potential economic uses.

Ideally, the decision to file a patent application, the scope of protection and the content of the description should be made by mutual agreement to avoid future problems and ensure maximum relevance of the application. Contract terms should include at least an obligation to consult and to co-ordinate prior to the filing of a patent application. If no agreement can be reached, each party should remain free to apply for patent protection based on results which its owns or jointly owns, provided that it does not include confidential information of the other party.

Allocation of user rights

Use rights for research purposes : One of the main functions of PROs is research. It is therefore essential for PROs to apply all the knowledge generated from collaborative research to further its research objectives without worrying about the origin of the funding.

Furthermore, as explained below, the scientific interest of certain collaborative work with industry is one of the main motivations of PROs in entering into research agreements.

Although the principle of freedom to carry out investigative research is embodied in common law in most European countries, it is advisable to reaffirm it explicitly in the collaborative research agreements. For example it may be that the parties wish to refine the exact scope of research freedom by declaring that PRO use rights for research purposes will not encompass development of commercial applications nor collaborative research with other industry partners. Those uses may be considered to be too close to the activities of the industrial partner as set out in the following section. However, it is for the parties to determine these matters and any contractual arrangements need to be carefully set up to ensure compliance with the European competition law regime.

Use rights for commercial purposes (including exclusivity and rights of first refusal): The right to use the results of the collaborative research for commercial purposes is, of course, the main consideration for the industrial partner and must be addressed properly. On the other hand, and to the extent publicly funded infrastructure and background IP is being applied, the PRO has a responsibility to ensure that the potential benefits to the public are optimised.

It is, for instance, not necessarily effective to grant exclusive use rights in all fields of application for all countries when the industrial partner is only interested in a specific field or is not committed to develop all applications if the research is successful. If exclusive rights are granted, then those rights cannot be granted to other partners or be used as the basis of further collaborative research with other industrial partners or other projects. This is an opportunity loss which should be adequately compensated by an exclusive licensee undertaking diligence commitments and offering financial compensation e.g. by way of either license fees or perhaps the recovery of full research costs plus an upfront profit in lieu of downstream royalties. A reasonable balance should be sought between the extent of exclusivity and the compensation due.

Confidentiality and the right to publish

It is essential that a fair balance be found between respect for appropriate confidential material and the right to publish research results. The ideal balance should enable prevention of prior disclosure of patentable material while not imposing undue delay on publication. Standard review mechanisms allow for both parties to review draft publications with a right to request delay for a maximum period of 60-90 days and the right to have proprietary confidential information deleted.

Fair share of the return from successful discoveries and inventions

One issue to be considered is the level of financial contributions to the PRO research costs. If the results do not contribute significantly to the scientific objectives of the PRO and do not represent novel science, then the nature of the relationship with an industrial partner is likely to be that of ‘contract research’ and the PRO function should be compensated at full cost of carrying out the work plus reasonable profit. PROs are not in business to compete with contract research organisations (CRO) and should not use public money to do so.

Conversely, if the collaborative research is of scientific interest to the PRO and if the PRO retains significant rights to the results (thus increasing its background IP and capability to add returns to the public), then the nature of the relationship is that of ‘Collaborative Research’ and the PRO may undertake the research in return for recovering its actual costs with an entitlement to share in downstream revenues which the industrial partner may gain from successful exploitation of the research results.

The level of financial compensation for the research performed by the PRO depends on a number of factors. Normally the PRO costs for collaborative research are calculated at direct costs plus a contribution towards its indirect costs (overhead). There is a wide variation of overhead rates levied by European PROs, ranging from 10% to 70% (or more) depending on countries. Even the latter is barely sufficient to cover the cost of infrastructure made available by the PROs. Some uniform standards should be adopted by European PROs to avoid unjustified price pressure. [However this

issue raises a whole range of financial management issues, which fall outside the scope of this report.]. In the meantime, it is recognised by the Group that it is in the interests of all the stakeholders to ensure that PROs can retain and motivate good scientists while competition between PROs should remain based primarily on quality of the science, not on prices.

Application of Revenues

First of all, it should be made very clear that the revenues from technology transfer are not used to fund the PRO as a substitute for government support. Even for the most successful US PROs, the license income is less than 10% of the public funding applied to research. For most PROs, it does not even cover the cost of managing the intellectual property and organising the technology transfer function.

In keeping with the above-mentioned objectives, any license income should serve several important purposes:

- *To motivate and reward the scientists having contributed most to the success of the research;*
- *To provide to the research unit at the PRO with "unfettered" money which can be used to pursue new ideas without going to the cumbersome and speculative process of tendering for research grants;*
- *To encourage development of the IPR management function in order to optimise research returns to the public.*

Pragmatism is the key to a successful licensing strategy. Requests for royalties or success fees must remain sufficiently low not to deter corporate partners from collaborating with PROs. As pointed out by some experienced technology transfer officers, this is a numbers game. It is better to conclude much collaboration with industry at low profit sharing than a few collaborations with higher profit sharing. The reverse is true as well. There is no point in a corporate partner bargaining down to a ridiculously low profit sharing if the quality of the science and the motivation of the scientists are affected.

Dispute Resolution and Enforcement

Since it is impossible to predict and cover everything in a contract, it is important that PROs consider how they will wish to resolve potential disputes that may arise. While it is always possible to resort to litigation in the courts, this is not always a satisfactory venue, given the complex issues that surround IPR and technology transfer and the publicity of the proceedings. Attention is drawn therefore to the World Intellectual Property Organisation (WIPO)[24], as an example of an alternative forum where alternative dispute resolution approaches such as mediation and arbitration may have been provided for in a contract.

General Contractual Issues

There are several other matters which the parties ought to ensure are discussed and agreed upon prior to commencing a relationship. An indicative list of these topics is set out below. However, there are many useful publications that describe in more detail the various options and implications open to the parties. Diligent performance obligations of both sides; Acceptability of reasonable financial aspects; Stability of research relationship; Conflicts of interest; confidentiality and right to publish; Governing law; Dispute resolution; Language.

[24] http://www.wipo.org

4.4. Case Studies

Examples of successful models of collaboration, with skeleton terms agreed, are included here in order to demonstrate some of the successful relationships, which can be set up.

CASE STUDY 1

Bilateral collaboration involving one industrial partner and one PRO: The PRO has existing expertise in a scientific field and the industrial partner wishes to facilitate more research in this field in order to have new options for the development of novel therapeutics. The company provides financial support underwriting the cost to the PRO of carrying out the three-year research programme. In return, the company is given an exclusive option to take a licence (on terms to be negotiated upon exercise of the option) to the results of the research. If the company exploits the results, then appropriate revenue sharing will apply. If the company either rejects the option or takes a licence with a limited scope, then the PRO will be able to seek other licensees for the technology. Patent management will be carried out by the PRO, in full consultation with the company for as long as the option exists. Access to background IP is included in the option. Publication of the results is permitted provided the company has the opportunity to review proposed publications and request deletion of its confidential information or request a delay to enable patents to be filed.

CASE STUDY 2

Consortium involving one PRO and several industrial partners, engaged in a pre-competitive research programme: The PRO has a broad portfolio of background IP and the expertise to further develop this. The industrial partners wish to access the background IP and to facilitate the development of further IP in the same field. Financial support for both the research and its infrastructure (laboratory fitting out) is provided by the industrial partners in equal proportions. In return they each receive a non-exclusive (or semi-exclusive since it was limited to the consortium members) option to take licences to the background and foreground IPR.. In this arrangement, since it was possible to determine the exact nature of both the IP and its end use by each of the partners, it was possible to negotiate the financial aspects of the licences that may be entered into if any of the options were exercised. Similar publication and patent management regimes to Case study 1 were in place.

4.5. Adoption of a 'Code of Good Practice' by PRO and Industry

The above practices should result in a balance between the interests of corporate partners and optimisation of the return to the public of the research carried out at PROs. The European tradition of technology transfer from PROs is much more based on direct collaboration between PROs and industry than the US model and this should be encouraged. The wide ranges of interactions, from consultancy and studentship interactions through to the collaborative projects, are valuable vehicles for exchanges of ideas and expertise. These exchanges must be continued, particularly in an era where there is greater mutual understanding between PROs and industry, which will encourage more of these relationships.

However, it is likely that for the foreseeable future, the negotiation of a balanced research agreement will remain difficult in practice for a number of reasons, including:

- the relative inexperience of PRO representatives in the management of IP;
- the difficulty to identify negotiators on both sides having the authority and or inclination to deviate from the historical model of IP transferring to the industrial partner;
- the poor bargaining position in which many European PROs are because of insufficient government funding;

The idea of adopting a Bayh-Dole look-alike directive in the European Community has been proposed on several occasions. Several European countries have adopted legislation inspired by it and the adoption of a single directive may have helped to create the European Research Space promoted by the European Commission. However, this idea is not generally supported by industry, which prefers more flexibility in its range of agreements with PROs.

All PRO technology transfer officers have experienced working with many companies that do understand the objectives and the constraints of PROs and can agree to balanced collaborative research agreements following the above principles. However, there are still many companies trying to gain unfair advantages from the perceived weak bargaining position of PROs and succeed in imposing inequitable agreements, which pursue short-term economic benefits. This should be a problem not only for PROs but also for the more responsible companies, which are, in effect, facing unfair competition from the less responsible ones. In the long term, such behaviour can be detrimental to Industry as a whole because it undermines the efforts of PROs to contribute to the economic use of the public sponsored research.

As a contribution to the solution, the Experts recommend the development by the representative associations of Industry and of PROs of guidelines encompassing mutually acceptable principles, which could be voluntarily adopted and monitored.

The Chemical industry amongst others offers a successful example of voluntary guidelines. A few years ago it faced the problem of the impact of environmental issues. The less responsible companies were not funding adequate environment protection systems thus creating an unfair advantage to the detriment of those more responsible, with the additional threat that governments would have to step in and impose more rigid standards. Industry reacted by adhering to the Charter of Responsible Care, which in effect commits them to follow general guidelines and to report on implementation. This initiative proved to be very effective and much more economical than the enforcement of rigid control systems.

The implementation of collaboration guidelines in the European Research Area could prove to be equally effective. A tentative draft outlining the potential elements of such guidelines is given below. The next step is to open the discussion between the representative associations in view of arriving at the widest agreement and support possible.

GUIDELINES FOR COLLABORATION BETWEEN INDUSTRY AND PUBLIC RESEARCH ORGANIZATIONS IN EUROPE (group proposal)

Background

The PRO recognises that the industrial partner's objective is to maximise financial returns to its shareholders. The industrial partner acknowledges that there have been many sponsors, both public and commercial, of the PRO background intellectual property and that PRO is responsible for optimising economic returns to the public. Both parties consider that their direct collaboration in research can be very effective in achieving their mutual objectives and agree that the following minimum principles will be reflected in their collaborative research agreement.

1. **Objectives:** All parties shall set out clearly their aspirations for the collaboration.
2. **Ownership**: First ownership of the results from collaborative research (Research Results) shall belong to the party generating it. PRO shall ensure that all its research associates involved in the collaborative research have assigned their rights to it. The allocation of ownership of the results generated jointly will be defined in the Agreement.
3. **Assignment of ownership**: As an alternative to licensing out the Research Results owned or jointly owned by the PRO, the Agreement may provide for the assignment of ownership of some or all Research Results or inventions based thereon to the Partner and the transfer shall be compensated by appropriate revenue-sharing.
4. **Use rights for commercial purposes**: In exchange for contributing to the funding, the Partner shall obtain use rights to the Research Results, which may be exclusive, limited to such applications, fields or territory, which it commits to develop. The PRO shall retain rights to use, with the right to sublicense, Research Results it owns or jointly owns, to the extent such use does not prejudice rights granted to the Partner.
5. **Use rights for research purposes**: The PRO shall retain the right to use the Research Results for research purposes, subject to a mutually agreed strategy.
6. **Access rights to PRO background technology**: The existence of PRO background IP is an essential consideration of the Agreement. Terms for a non-exclusive license to such PRO background IP, to the extent necessary to affect the Use Rights, will be agreed in writing in the Agreement
7. **Management of IP**: The PRO is initially responsible protecting its Research Results by available means, including patent applications when these are warranted by their commercial potential. Terms about mutual consultation and downstream decision-making will be included.
8. **Confidentiality/ Publications**: All parties agree to mutually respect the confidentiality of information owned by another party. Publication by the PRO of results of scientific significance shall not be delayed beyond the time reasonably required to apply for patent protection and shall not contain industrial partner confidential information.
9. **Compensation**: The level of financial support to the PRO by the industrial partner(s) shall take into account the applicable regulations, the costs of the PRO, the amount of work, the scientific value of such work, the nature of the results, the rights retained by the PRO and the importance of any background technology.
10. **Profit Sharing**: For research involving a significant intellectual contribution from the PRO, the parties will allow for reasonable profit sharing where there is successful utilisation of the Research Results by the industrial partner.

5. CHAPTER FIVE

The Creation of New Companies Based Upon PRO Technology

The creation of spinout and start-up companies is increasingly being encouraged as a means of maximising the benefits of IPR to the European economy. This chapter will identify some of the issues where policies, practices and training for PROs need to be established. Again the perspectives of the different stakeholders need to be set out here in order to facilitate common understanding and achievement of agreed goals in setting up new companies.

Key Messages

Setting up new companies to develop early stage technology has many advantages for the PRO, its region and the technology itself as well as meeting the market's need for later stage technology rather than early stage, provided it is done in a professional way

The involvement of a PRO in this process requires professional skills, including full understanding of the business opportunities and funding implications for new companies.

More so than with other technology transfer activities, this process is one which requires several partners, since the key ingredients are access to the technology, access to infrastructure, access to funding for the company and access to key management teams to run the new company.

Background

Technology transfer increasingly happens by virtue of new industrial companies being created as a result of research activity in PROs. This process, where tangible IPR from within a PRO is further developed and commercialised by way of a new company, is the subject of this chapter.

However, it should also be noted that in addition to direct IPR-based companies (spin-out companies), there is also a role for PRO's in the facilitation of new companies where people, infrastructure and general know-how rather than tangible IPR are the contribution of the PRO. These are often referred to as "start-up" companies. Where a PRO has a proactive nurturing technology transfer culture, a successful by-product is often an additional range of start-ups.

5.1. Importance of Spinouts in the Technology Transfer Process

Next to direct collaboration with industry and straight licensing, the creation of new spinout companies is one of the most efficient process of technology transfer and creation of economic value. This form of technology transfer is one that requires effective communication and mutual support of several of the stakeholders if the process is to be successful. In addition to the PRO objectives identified above, it may also be helpful to clarify those of the other key stakeholders.

The term PRO Spinout Company[25] as used herein is defined as any new company created mainly for the purpose of exploiting technology originally developed by the PRO. In most cases, some of the scientific personnel involved in the creation of such technology leave the PRO and join the new company, effecting thereby the technology transfer. This transfer of personnel can be on a permanent or temporary basis. In addition, many of the senior academic inventors often take a role in the new company but also retain their academic positions.

Where there is a spirit of entrepreneurial activity, academic researchers or third party entrepreneurs will frequently set up new companies close to a PRO. They wish to have links with the departments of a PRO although the founding technology will not have come entirely from the PRO. This has a huge economic benefit to the local community and creates opportunities for downstream IR/research and consultancy relationships with the PRO. Other stakeholders also benefit, since there are socio-economic gains, employment opportunities and investment opportunities for Venture Capitalists.

The experience of those PROs involved for many years in technology transfer, as reported from several studies, shows that the creation of spinout companies is potentially the most important means to achieve the above objectives, for the following reasons:

1. In most cases, the inventions conceived in PROs are still very far from potential applications. The proof-of-principle and the economic feasibility have still to be made. In such circumstances, it is fairly difficult to convince industry to take a licence and invest in the development. The technology transfer, when possible, is then made on conditions that are not very favourable to the PRO and the inventors. The alternative to create a spinout company allows:

    a. To externalise the development process from the PRO where it may not fit properly or may not correspond to the scientific objectives and culture;
    b. To obtain development funding not available to pure research institutions in order to finance part of the development costs;
    c. To participate to European Development Programs such as FP5 or FP6 as industrial partners;
    d. To provide a new opportunity to the researchers with entrepreneurial ability and motivation.

2. It is also fairly frequent that the technology available from the PRO is in the form of know-how, rare but not unique and difficult to license out on attractive terms. The alternative is for the researchers with such know-how and entrepreneurial motivation is to seek employment with commercial companies in the same field. Frequently, this involves moving to another country if the local environment is poor in terms of technological companies. The creation of a spinout company is then the only logical alternative to facilitate the development of the technology locally.

3. Experience also shows that spinout companies tend to maintain direct collaboration links with the originating PRO and to settle in the vicinity of the PRO, such as a Science Park. This form of technology transfer turns out to have a larger local content than the other forms and to contribute more directly to the local economy and to the support of the research function of the PRO.

4. On purely economic terms, the potential returns as capital gains on spinout equity participations are likely to be significantly larger than the license revenues when those are

[25] There are different definitions of Spinout companies. For a typology and examples of different forms, see for example Clarysse et al *Spinning off new Ventures – typology of strategies in Europe*, 2002, available from http://www.iwt.be/obs/obsdef.htm

possible. This is the logical outcome of the value added by delivering the proof of principle when it works.

In many cases, the fate of spinout companies is to be acquired by larger companies with attendant capital gain for the PRO and for the entrepreneurs. Here the technology transfer process has been successfully achieved for a technology, which, without the creation of a spinout company, would not have been developed. Spinout companies can therefore be considered as important vectors of technology transfer.

In other cases, there are several examples of spinout companies having grown independently through successive rounds of capitalisation and public offering to become leaders in their field on international level, while maintaining close links with their originating PRO.

5.2. Trends in the Creation of PRO Spinouts

The direct involvement of PROs in Europe in spinout generation is fairly recent.[26], beginning in the late 80s and is now spreading progressively throughout Europe. Prior to that, university spinouts were created almost spontaneously, without much support (yet sometimes even with opposition) from the university or PRO.

Increased involvement is due largely to the progressive assignment across Europe of the intellectual property from public sponsored research to the PROs and to the progressive availability of seed capital. The role model played by several remarkable successes also had some influence[27]. The direct involvement of certain European PROs, notably in the UK, the Netherlands, Belgium and Germany, in the creation of spinout companies is comparatively larger than in the USA.

The following table compares the rate of spinout creation in the UK, US and Canada from data obtained from the AUTM and UNICO-NUBS surveys:

Indicator	**USA**	**Canada**	**U.K.**
Number of PROs responding to the surveys	140	19	79
Number of Spinouts created/Year	203	35	175
Number of Spinouts created per university/Year	1.45	1.84	2.22
Sponsored research expenditure per Spinout created	133 M Euros	37 M Euros	13 M Euros

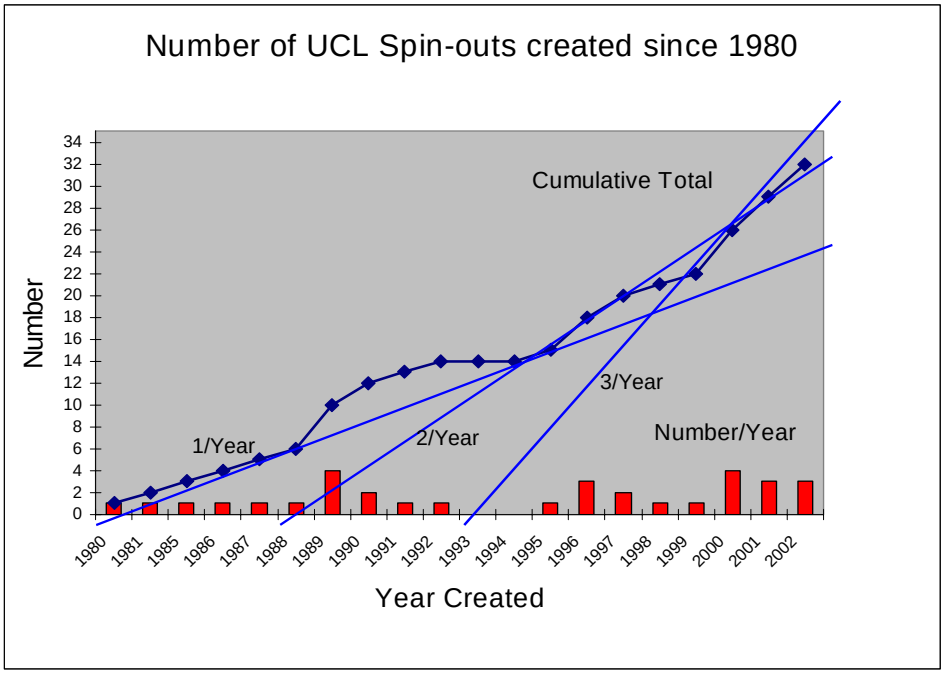
Source : UNICO-NUBS survey FY2001

Although great care should be taken when comparing the number of spinouts, since the nature of such spinouts may be different, this table would indicate that the rate of spinout creation is comparable in the UK with USA and Canada, while the amount of underlying research expenditures is substantially less.

[26] A fairly extensive survey on the creation of spin-offs was conducted by OECD in 1999: STI Review N°26 *Special Issue on Fostering High Tech Spin-offs: A Public Strategy for Innovation.* OECD 2001

[27] Clarysse et al. Op. Cit.

A typical example of university involvement in the creation of spinouts is illustrated by the experience of the Université catholique de Louvain (UCL), which is representative of an average size research university. It has been active since about 1980 in technology transfer. The graph hereunder shows the number of spinouts created each year since that date. In the beginning, there was no direct involvement of the university in the creation of spinouts. They were created spontaneously from UCL technology at the rate of about 1/year. From 1990, UCL increased its involvement by creating a seed capital fund of about 1.5 Million Euros managed by a limited liability company, SOPARTEC. The rate of creation increases to about 2/Year, half of which with funding by SOPARTEC. In 1999, SOPARTEC was converted into a technology transfer company managing the university intellectual property, in addition to seed capital. The financial means increased substantially from capital gains on earlier investments (one successful IPO). Since then, the rate of creation has increased to 3/Year, most of which with active coaching and financial support from SOPARTEC.



This example, which is not unique, would suggest that the rate of creation of new Spinout companies based on PRO technology could be substantially increased with a more active involvement including a combination of incubation, coaching and seed capital. Certain larger PROs with longer involvement in spinout companies' creation can help create spinout companies at the rate of 1/month or more.

5.3. Key success factors in the creation of PRO spinouts

The creation of spinouts is by no means a simple process. Technology derived from the PRO needs to be supported by the creation of a team of industrial, marketing, financial, legal and other skills which may not be initially present in the initial technologically expert team. Outsourcing such skills or hiring the experienced professionals is generally an expensive proposition. Seed capital is still hard to find.

Experience from the PROs which have been most active in the creation of spinout companies, shows that it is possible to increase the rate of "spontaneous" creation of spinout companies by a factor 2 or 3 by a combination of measures:

1. Key entrepreneurs and an entrepreneurial spirit;
2. Continuous support from the parent PRO;
3. The provision of pre-seed and seed capital and of development loans;
4. Expertise of the PRO technology transfer and investment functions.
5. Coaching and support in dedicated technology incubators;
6. Improving education and entrepreneurial training for the management of SMEs

These factors are more fully discussed below.

Support from PRO

The support of the originating PRO is very important to induce entrepreneurs to take the risk of starting a spinout company. This support is demonstrated by a combination of factors:

- Stating clearly that the creation of spinout is one of the policy objectives of the organisation;
- Fostering a spirit of enterprise in the scientific community;
- Encouraging by supportive measures the scientists wishing to be involved in a spinout;
- Making the access to the technology available and affordable;

Apart from mechanisms which create more awareness among PRO researchers about the possibility of founding technology based companies, supportive risk reduction measures can contribute to reaching a significant level of new ventures (for example, part-time contracts for researchers interested in founding a spin-off or a 'leave of absence' scheme which would guarantee the researcher the return to his former position should the spin-off idea fail) [28]

The technology transfer process is not finished once the spinout company is created. Rather, it actually starts. Unless all the key scientists are available to work with the spinout company in at least its infancy, the company is not likely to either succeed or attract funding support. The transfer of technology in the form of technological expertise, know-how, goodwill and contacts, is likely to take some time and require some work on both sides. Since the PRO is likely to wish to retain its ability to carry out research in the field of expertise of these individuals, it is important that the aspirations of both the PRO and the inventor are recognised. Some inventors may wish to dedicate part of their time to the early stage commercial development of the technology and therefore seek to retain a parallel PRO position or to return after a fixed period within the new company. PRO's should ensure that mechanisms exist to accommodate these alternatives. However, due to potential conflicts of interest, whatever the nature of the role, it should be transparent to all concerned.

The technology is not frozen on the date of incorporation and will continue to evolve, as more research is made by the PRO and other research organisations worldwide. Since the spinout company will concentrate in the beginning on the development of commercial products, it may have little time or internal resource to spend on speculative research, which is essential for a pipeline of new products. The PRO may then play the interim role of research department for the spinout as it may already be doing to some extent for larger companies under industrial research collaborations. In practice, access to future IPR in defined fields may be made available to spinout companies under a right of first refusal to licence new technologies discovered by the PRO in the well-defined field and territory. It should also be clearly established that the relationship between the new company and the originating department might require access to grant back licences to developments of the technologies. Defining such access should be a priority in order to maintain clarity of rights and expectations. Forming a spinout company is an emotive and emotional experience for those directly involved and those on the periphery, so as much as possible should be done to ensure that appropriate information and expectations are managed effectively. As the facilitator, this is a crucial role for the KTO.

[28] *Good Practice in the Transfer of University Technology to Industry:* http://www.cordis.lu/eims/src/eims-r26.htm

However, active involvement of PROs in creating spinout companies has also been criticised as interfering with their relationship with existing industry players. Some companies have expressed the concern that the know-how gained by PROs in the framework of collaborative research may result in creating additional competition for themselves. On the other hand, starting spinouts will need to establish strategic partnerships with existing industries in the early stages in order to succeed. The PROs will have to define a delicate balance between the needs of their spinouts and the collaboration with existing industrial partners. Indeed, it has been demonstrated on numerous occasions that novel technologies are very difficult to licence into certain industries and that the only way to have them explored is by setting up a new company. Furthermore, specific experiences of software have shown that useful technologies are only made available by new companies. Furthermore, the biotech industry exists and thrives in order to meet the needs of broader industry as its customer, as distinct from ordinary members of the public. Start-ups and spinouts are essential in this supply chain.

Capital

Pre-seed capital is needed during the 2 or 3 years of maturation prior to incorporation of the new spinout company in order to support the would-be-entrepreneurs and to fund the minimum market analysis, competitive analysis, secure intellectual property access and freedom of exploitation, assemble team. This phase is important and often forgotten in the public support schemes.

Seed capital is needed at the time of incorporation of the spinout company. It should be sufficient to fund the company at least through the period needed to make the proof of principle of the economic value of the business concept and of the underlying technology. The duration of this period may vary from a low 2 years for ICT technologies to a long 5 years or more for biotechnology or pharmaceutical companies. The required capital would also vary according to the business concept (product or service) and to the technology, from a typical low figure of €250.000 to €5 Millions or more. At any rate, the amount is generally in excess of the means of the entrepreneurs and too low (and too risky) for the Venture Capital.

The network of Business Angels is spreading and getting more organised in Europe. This could potentially become a new source of seed capital. The general opinion of the experts is that this form of equity funding is not yet well adapted to technology companies.

Development loans, which are granted by local governments to fund the development of new products, are very useful. They can typically cover between 50% and 80% of the development costs and must only be paid back in case of successful commercialisation. As such, they can be considered as quasi-capital, which is not dilutive and much less expensive than venture capital. In effect, such loans may multiply by a factor 2 to 5 the initial capital. The development grants from the EC are in this category. Unfortunately, the conditions for access are made difficult from SMEs. In particular, the applicant must provide guarantees equivalent to the down payments, which negates the leverage effect.

Bridge funding is needed after the initial seed or proof-of-principle stage to bring the company through the break-even point into self-sustaining stage. The alternative of increasing the seed capital may not be possible or desirable because of dilution effects. The problem is that the amount of capital to be raised may still be too low for Venture Capital to justify the diligence and closing costs. The other problem is that the amount is becoming too high for typical seed capital funds. In most cases, they are nevertheless forced to follow or face strong dilution. The availability of bridge funding is becoming a more serious problem than that of seed capital.

Expertise of PRO technology transfer and investment functions

The setting-up of a spinout company requires more than the command of the underlying technology. As pointed out before, there a number of other skills and business experience which are required to succeed. In the ideal world portrayed in textbooks, each start-up company must have from the start the

ideal team of people with skills, leadership and experience. This is almost never the case in PRO spinouts, and the necessary expertise will have to be supplemented by the coaching and support functions organised by the PRO.

This requires experienced professionals with industry experience not easily found, nor compensated, within a university environment. To alleviate this problem, several PROs have elected to set-up a separate limited liability company (Technology Transfer Company or TTC) combining the functions of technology transfer and seed capital investment[29]. This makes sense, because the skills required for technology transfer and for structuring new businesses are similar. Both require understanding of business sectors and experience in business development. The functions of coaching and of administering a portfolio of investments are also very close. Both require monitoring of the operations and assistance in networking and facilitating strategic alliances. Most UK PROs have chosen this model and are federated within the UNICO organisation. The model is now spreading to continental Europe. By contrast, it is almost non-existent in the US PROs, which continue to rely mainly on Technology Transfer Offices (TO).

The organisation of Technology Transfer Companies (TTC) requires the reunion of three elements:

- a seed capital fund, preferably evergreen or with a long investment horizon;
- a team of business developers with both technology background and industry experience;
- financial support for several years before balancing the operating expenses with the license and management fees revenues.

There are economies of scale involved. Only the larger PROs can justify a dedicated TTC and the smaller PROs should be encouraged to federate their requirements[30].

Technology Incubators

The concept of technology incubator is to concentrate into a single location the initial space requirements of spinouts, the infrastructure and all the support functions useful for start-up technology companies. The functions of coaching and of follow-up of investments are preferably based in the same building. Much of the support comes from exchange of experiences between start-up companies. The successful technology incubators are much more than a building. The building is comparable to the reactor in a chemical process. It does not replace the raw materials but creates the appropriate conditions for the reaction between those materials to take place.

Interest in university-sponsored business incubators stems from the significant potential of the concept. The concept holds out the possibility of linking talent, technology, capital and know-how to leverage entrepreneurial talent, accelerate the development of new technology based firms, and speed the commercialisation of technology.[31]

Most technology incubators are not specialised in any single technology and would support technology spinouts in various fields. They are ideally located next to the originating PRO in order to facilitate the transition and maintain close links with the research, which is continuing at the PRO. They are sometimes located in the Science Park, when the PRO has one, to which they are a natural transition.

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[29] *The Management of Intellectual Property in Higher Education – Production of a Good Practice Guide. A Project for UUK and AURIL with support from the DTI and the Patent Office –* http://www.sqw.co.uk/data/IP.html

[30] *New report spells out potential of spin-offs and start-ups for UK PROs*

[31] A*ssessing and managing the university technology business incubator: an integrative framework.* Journal of Business Venturing, 12 – 1997

Some technology incubators are specialised by technology in order to benefit from specialised infrastructure, which can be shared for cost effectiveness. Those incubators are generally expensive to build and require significant government funding. They also require a larger concentration of companies in the same field, which must be recruited on a wider basis than just a single PRO. In this case, the term business accelerator is probably more appropriate.

Whether general or specialised, the technology incubators cannot be created and survive without government support. This is another area where public money can leverage the technology transfer from PROs.

Access to Markets

Almost by nature, technology based companies need access to wide geographical markets in order to justify the technology investment. Even though the European Commission has substantially reduced the trade barriers between European countries, the commercial development of Spinout companies outside their reference national market remains difficult. It generally involves the setting up of reliable distributors capable of supporting the technology or of expensive branches. In this sense, European technology spinouts are still at disadvantage compared to their US counterparts and many of them would thrive if placed in the US environment.

The networking of PROs spinouts in different countries with complementary products should be encouraged in order to share the commercial investment.

Education and training

There is a general need for young entrepreneurs with a curriculum well adapted to managing SMEs. The current education at most PROs is more attuned to the needs of specialised functions in large companies. However there is a growing recognition across Europe that specific dedicated entrepreneurial programmes can lead to a gradual change in culture, with the result that more mew companies are formed. In the UK, the Department of Trade and Industry is actively encouraging this and a series of virtual institutes has been funded in order to maximise existing experience, to encourage the development of training modules and courses for undergraduates and companies alike and also to provide for the first time direct, dedicated support to undergraduates who wish to set up their own companies.

5.4. Conclusion

Generation of new companies is a complex and high-risk exercise. However, it has been recognised that PROs may be a good source of opportunities for such new companies. Many of the stakeholders, particularly those in the public sector are keen to stimulate this activity and more so here than in any other aspect of technology transfer is there a need for a strong team approach to achieve the goals of economic growth. Hence the close interaction among PRO, local government and private sector finance in order to create and maintain the necessary culture, infrastructure and environment for new companies to be set up and be given the best chance to thrive.

6. CHAPTER SIX

Planning for a KTO

Experience shows that it takes many years to build an effective technology transfer function within a PRO. The PRO expertise in IPR varies widely across Europe. The implementation of a proactive IPR management system within a PRO has far reaching implications, which are often underestimated in the beginning. The main challenges are: ensuring a clear commitment by senior management in a PRO for technology transfer activity; managing ownership regimes of public sponsored research results and inventions such that a single entity has responsibility for the IPR; engaging the commitment of the PRO scientists to the model and developing a body of skilled professional and maintaining effective relationships with the necessary stakeholders.

Key messages

Knowledge Transfer is an important function, which needs to be professionally managed.

The function needs to be adequately resourced, with a long-term commitment to provide access to the necessary funding and expertise.

A KTO enhances the efficiency of the PRO knowledge transfer function to maximise benefits to society.

The most effective approach to knowledge transfer involves the KTO and the researchers working as a close team.

The skills needed to engage in knowledge transfer can take many years to acquire and so it is important to facilitate exchanges of best practice, not only among PROs but also with industrial and professional organisations.

6.1. Determine the Mission of the KTO

The term Knowledge Transfer Office (KTO) is meant here to encompass the different organisations, which are active in transferring technology or knowledge from PROs and other research institutes, which are mainly supported by public funds. The form of such organisations may vary from dedicated offices within university administration to semi-autonomous limited liability companies.

Before deciding what type of KTO function is to be set up, it is essential for a PRO to establish a mission that encompasses the objectives of the PRO. The KTO should then be given this stated mission to deliver. To be effective the mission must be understood and agreed to by: (1) the Director and the staff of the KTO; (2) the Board of Trustees or other group that has overall responsibility for the university; (3) the researchers who are expected to collaborate to the innovation process; (4) the industry which will eventually develop and market the new products; and (5) the national and regional governments that are defining the public policies and provide most of the funding. The missions of TOs and what they can achieve are still largely misunderstood by the many stakeholders with whom they interface, which could be said to include all of the following: **Academia** (Management (administrative and academic); **Departments** (Professor(s); researchers; student(s) and the TO itself); **Government** (Local, National and European); **Service Providers** (Patent Agents/Lawyers); **Industry** (Large multinationals, SMEs and start-ups/spin-offs); **Industry personnel** (Research & Development,

Business Units, Executive Management, Patent counsel, Technical Staff, Financial Controller, Law Department); **Finance** (Business Angels, Venture Capitalists (Institutional), Banks); **Entrepreneurs; General public.**

Although the detailed missions of KTOs may vary to some extent according to the local environment, they all share one central mission, which can be defined as follows:

The central mission of a Knowledge Transfer Offices is to increase the efficiency with which PRO discoveries and research results can be optimised for maximum benefit to society.

The Mission Statement

In crafting a mission statement, several possible components should be included and evaluated with one key objective designated as the driver of primary importance. They include:

1 To facilitate the transfer of publicly funded discoveries into new products and services for public use and benefit.
2 To promote regional economic growth and job creation.
3 To reward, retain, and recruit faculty and graduate students.
4 To create (new) relationships with industry.
5 To generate new funding support for the university and/or faculty from sponsored research, consulting opportunities for faculty, and donations of money or equipment.
6 To serve as a service centre to the university, faculty, students, and staff on all areas related to intellectual property and entrepreneurship including providing seminars and consulting assistance when requested.
7 To actively facilitate formation of university-connected start-up (spinout) companies.
8 To generate net royalty income for the KTO, inventors, and the university.

All KTOs should include the core mission (1), since this is the legitimate basis for managing intellectual property that has been generated mostly from public funding. Moreover, the corresponding policy should be to protect inventions and diligently develop inventions only when this would not be expected to occur by simply putting the results in the public domain. If we define innovation as the process that converts discoveries from research into the development of new products, *the mission of the KTOs is to help PROs to take a pro-active role in the innovation process.*

The promotion of regional economic growth and job creation tends to be more prevalent for "public" PROs that receive a portion of their financial base from regional taxes. This provides a rationale for giving preference to regional industry in licensing technology and also a greater incentive to form start-up companies in the region that will contribute to regional economic growth.

Once established, it is appropriate to review the mission statement periodically to ensure it is accurate and that all parties concur that it reflects the priorities and goals of the PRO.

6.2. The Keystone of a Successful Transfer Office: Maintaining Strategic Relationships

Good practices should be developed in conjunction with all stakeholders, particularly with e.g. industrial partners who are also engaged on their own behalf in managing IPR portfolios. Exchanging best practice is essential. The professionalisation of KTOs is driven by the relationships with other stakeholders and the following perspectives should be borne in mind at all times.

Relationship with Researchers

The inventor(s) play a crucial role in the process, and without their active involvement and support, it would be very difficult to achieve any measure of success. They must make the effort to reflect on the possible uses of their discoveries, disclose inventions, help identify potential licensees, participate in obtaining strong patent protection, host visits of potential licensees, and on a voluntary basis, provide the know-how and show-how that is sometimes crucial to successful commercialisation of a technology. These are typically very busy people, so it is important to respect this and not make undue demands on their time. For instance, the invention disclosure form should be simple and easy to complete and KTO staff should be readily accessible to researchers.

The KTO should be the primary source of service and assistance to PRO faculty, staff, and students on issues related to intellectual property (IP). This includes serving on committees that are creating or reviewing intellectual property policies and procedures, answering questions related to IP, providing seminars as requested on IP issues or on how IP is handled at the university, providing support for student projects that involve IP, and in general being the place people go whenever an issue about IP arises. This is a very important service to members of the university community and determines its relationship among the faculty, students, and staff.

One of the most valuable contributions of a KTO to its PRO is the new relationship with industry that it facilitates, from which many benefits can flow. As well as the possibility of downstream royalty income, there are more immediate opportunities such as sponsorship of research, consulting opportunities for faculty, the hiring of students when they graduate (particularly co-inventors on the licensed patent[s]), and possible donations of money or equipment.

Several regulations concerning Public Funded Research and Patent Statutes impose to share the benefits from licensing inventions with the inventors. This is intended as a matter of equity and as an incentive to motivate researchers. A recent study finds that PROs that give higher royalty shares to academic scientists generate more inventions and higher license income, controlling for other factors including university size, quality, research funding and technology licensing inputs.[32]

Good practice tips

- Encourage researchers to review prior art and patents before engaging in new research to avoid repeating work done already (it is estimated that at least 30% of the research undertaken is duplicating work already carried out).
- Implement confidentiality procedures in sponsored research or in projects that may lead to possible commercial use.
- Review certain papers before publication in order to identify patentable inventions (in this respect, the grace period would be very useful).
- Assessing inventorship and ownership of inventions.
- Manage invention disclosures and filing patent applications efficiently.

PRO Administration

The interests of the KTO should be aligned with the interests of the PRO. This means the KTO operates in a manner that supports the objectives of the PRO, where rapid dissemination of research discoveries via conferences and/or publication is very important to the faculty and students. Any delay in such dissemination to protect intellectual property rights would need a very, very strong justification. The KTO must also be careful that research, licensing, or other forms of agreements do not entangle future intellectual property rights in a way that compromises the ability of a faculty

[32] Centre for Economic Policy Research, *Incentives and Invention in PROs*, 2003, http://www.cepr.org/pubs/new-dps/dplist.asp?dpno=3916

member to obtain sponsored research funding. And in creating or maintaining relationships with industry, the KTO must be recognised that a given company may have a number of important relationships with the PRO e.g., participation in collaboration agreements, membership in Affiliate Programs, major donations of money or equipment, and so on) which must be taken into account should the KTO find itself in a disagreement with a potential or actual licensee.

Good Practice Tips

- Avoid and manage potential or actual conflicts of interest.
- Monitor the provisions of collaborative agreements (research and/or licence) to ensure that expectations of all sides are being realised.
- Ensure that the mission and objectives are adhered to and updated where necessary.

Relationship with Private Sector

Positive relationships afford industry greater opportunities for access to a huge range of potential links with PROs. These include research relationships, consulting work with faculty (and sometimes graduate students as well when approved by their advisor), feedback about usage of new specialized research equipment and many other benefits. The KTO should be aware of such opportunities and can effectively act as a catalyst for introductions, while it remains the discretion of the researcher whether or not to pursue such opportunities. However, in dealing strategically with companies (young or old) over a period of time, the growth in mutual understanding of aims and methods of working can ensure that relationships are more likely to be fruitful. It is important that both parties are aware of the concerns and limitations of the other party, and openly discuss such concerns in order to find creative approaches to respect such positions.

With regard to the formation of new entities, the KTO must make clear what role it will, and will not, play in the formation of new companies utilising university technology and/or university people. Passive involvement is the most common model for example in the USA where KTOs provide referrals to resources that can assist in the start-up process without further active involvement. In Europe, however, involvement is often much more active, including some or all of the following: helping to write or actually writing the business plan, incorporation of the company, finding initial seed funding, recruiting the management team, and securing the first round venture funding.

Good Practice Tips

- Find out about the interests of companies and establish contact with their business groups.
- Negotiate fair collaborative agreements with industry.
- Negotiate realistic licenses and licence options.
- Professionally manage the PRO's role in the creation of start-up companies.

Relationship with Government(s)

The remit of government is to look after the collective best interests of the people it represents. In this context, they legislate and develop implementing regulations to create a better standard of living environment for the citizens. In order to do so successfully they must listen to the community, therefore PROs should ensure that they maintain dialogue with government representatives so that information is mutually exchanged about issues relating to PRO functions.

Good Practice Tips

- Find out what government departments are involved and establish contact with their personnel.
- Be transparent about the challenges as well as successes in KTO functions.
- Ensure any dialogue about measures of success takes account of all missions of PROs.

6.3. Determine the Structure of the KTO

The next task of the PRO is then to determine what resources are needed to fulfil the mission and to decide how those resources will be deployed.

Across Europe and the US there are several different organisational structures established to carry out the functions of a KTO. These fall into (3) categories: those which provide a dedicated (in-house or PRO corporate subsidiaries) service for one PRO; those which have been created as separate corporate entities to manage the innovation process for a number of PROs (either in a geographical or technical area) and those which are established as for-profit service entities.

There are a range of practical issues, which show the relative strengths and weaknesses of each of these models. Those in-house departments may find it difficult to be sufficiently resourced to provide the range of support for its PRO and may have initial difficulties in establishing credibility with the academic staff. However once a good reputation is gained, the in-house KTO makes a very powerful team when alongside the inventors. A slight advantage is perceived for those responsible for running externally established not-for-profit KTOs in the freedom from adherence to the PRO decision-making processes and potentially restrictive salary scales.

Those organisations with a wider brief to support to a number of PROs acknowledge the challenges of being physically remote from the researchers as well as dealing with even larger numbers of researchers than can be evenly managed. Without the robust personal relationship with inventors it is difficult for technology transfer opportunities to develop and grow and may even lead to disappointed expectations. A recent review of such support in the UK by the Wellcome Trust concluded that the optimum model for achieving the goal of transferring new technology is for local KTOs to work closely with the Trust, such that there is a division of appropriate skills and expertise. This mirrors other experiences where a certain amount of centralisation of resources can be effective, where the remote services are of a more technical or financial nature.

The for-profit service organisations such as RCT and BTG provide a pragmatic, financially motivated service, such that potentially significant revenue attracting inventions are supported with robust patent costs and aggressive marketing. There is no support for highly speculative or smaller market focused inventions, no matter the potential benefits to society. Therefore while selected inventions (or indeed organisations with only occasional inventions) may find such a service appropriate, it is unlikely that such organisations can achieve the objective of securing effective technology transfer from PROs.

The rationale for selecting the most appropriate model will be determined by the best match with the mission of the PRO. If we broadly see the missions as being directed towards either income generation or transfer of knowledge and recognise the potential conflict between these objectives, we begin to see that establishing the vehicle best equipped to meet the chosen mission is essential. Stanford provides the following illustration of the dilemma:

Following the formation of the Stanford Management Company (SMC) to manage the income producing assets of Stanford, such as the endowment, real estate and income producing properties donated to Stanford where the compensation of SMC employees is linked to the SMC financial results in their particular area, the core mission of their KTO was debated. If Stanford's KTO were to become part of the SMC, there was great concern that sufficient support would not be given at all to non-revenue producing services, and the focus of KTO licensing people would be directed only to faculty and departments likely to produce inventions with significant commercial potential. Stanford decided that income generation was not the primary mission of its KTO and therefore did not absorb the KTO within the SMC.[33]

[33] J. Sandelin, Op. cited.

While generating net royalty income for the KTO, the inventors and the university is an important goal, the Group would strongly advise against making this the primary mission of the KTO. There are several reasons for this recommendation, not least of which relates to the fact that public sources are funding the research work and so benefits of the results should be made available for the good of society. However the same source of funding means that if there are financial benefits from such research then these should not be retained solely by industry.

The balance of achieving these interdependent goals of transferring technology so that it can be further developed as well as that of sharing (in a small way) its financial success is a function that can only be achieved if decision-making about the innovation process remains with the PRO. The PRO must be seen to be providing a full service support to its research base, from providing access to information about IPR, to assisting in the identification of new inventions, to seeking development funding, to finding commercial exploitation routes for the technology and above all, working to enhance the overall mission of the researchers in their continued pursuit of new knowledge and should not delegate strategic decision-making about its IPR portfolio.

6.4. Funding a KTO

Assessment[34] of the effectiveness of technology transfer offices in the USA since the enactment of the Bayh Dole Act shows that one of the most determinant factors in predicting effectiveness is experience. The same study shows that it takes at least 10 years to develop enough royalty revenues to cover the cost of the IPR management function. Most European PROs cannot afford such investment unless the costs can be underwritten without a short-term self-funding aspiration.

The Canadian report on commercialisation of IPR from PROs[35] estimates at 5% of the research budget the cost of running a professional IPR management function. The proposed investment of 50 Million CAD per year over 10 years to support university TOs or 500 Million CAD is expected to yield a gain of 4.4 Billion CAD for the Canadian economy[36], of which only 120 Million CAD in royalties to the PROs. Dutch studies show that the financial costs of running an effective technology transfer office may run at 7% of a research budget.

In light of the general financial pressures on the teaching and research functions of European PRO's it is unlikely that many of them can bear the burden of such a long-term financial investment alone. That is why it is so important that all the stakeholders accept the need for effective IPR management. In particular, additional public sector funding ought to be made available to ensure that this additional function is fully integrated as a legitimate role of a PRO. There should be no dilution of teaching or research functions to pay for technology transfer functions. It will be necessary to ensure that where there are direct costs associated with the downstream development of technology that appropriate cost recovery mechanisms are in place.

Because there is an evolution of activity, with a time lag between investing resources in technology transfer and ultimately sharing any financial benefits that may accrue, PROs must be able to establish their resource funding to reflect this reality. Some of the more 'successful' PROs may eventually generate sufficient royalty income to support the core activities, but these are in the minority.

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[34] Everett M. Rogers, Jing Yin and Joern Hoffmann : *Assessing the Effectiveness of Technology Transfer Offices at US Research PROs.* Journal of the Association of University Technology Managers, Vol. XII (2000) 47-80 – http://www.autm.net/pubs/journal/00/assessing.html

[35] *Public Investments in University Research: Reaping the Benefits.* Report of the Expert Panel on the Commercialisation of University Research, May 4, 1999, http://acst-ccst.gc.ca/comm/home_e.html

[36] Presentation of James W. Murray at the OECD Workshop on Management of Intellectual Property Generated from Public Funded Research, December 11, 2000 – http://www.oecd.org/dataoecd/13/41/1903892.pdf

There are several models of financing KTOs and these reflect the current state of flux about what the functions of a PRO should be, hence unresolved questions remain about where responsibility for funding this activity should lie. Many of the stakeholders have begun to play a more active role in funding the activity. The story so far indicates the following trends.

PRO: Traditional public funding has been always to provide PROs with teaching and research resources, with additional research frequently being supported through competitively awarded research grants. However, there remains a time lag between the recognition that technology transfer and IPR management have also become necessary functions of PROs in pursuit of their overall missions of generating and disseminating new knowledge for the public benefit so that in few countries is there additional public funding provided. This means a dilemma for PROs. Some have no funds available. Others, whose senior management has embraced the transfer mission, have had to find resources from within their budgets to provide access to a KTO service. This generally involves a small team, with the hope that it in turn will identify additional funding sources. Income generation by a KTO is at best a long-term strategy and is universally accepted as being an inappropriate basis for sustaining the KTO function, unless or until a transfer leads to a major financial success. But since PROs are transferring technology opportunities rather than actual products, income generation is rarely going to be more than a lucky ´side effect´ of the process. If it is accepted that the whole process is key to improving the social and economic health of the community at large, then the service needs to be effectively resourced.

The direct or indirect funding by PROs is generally a combination of the following:

- the allocation of a budget from the PRO;
- a portion of the net royalty income on licensed technology;
- a portion of realised capital gains on spinout equity participation;
- an overhead on collaborative research agreements with Industry;

Care should be taken in putting not too much emphasis on license revenue because this may have the indirect effect on giving preference to the technologies most easily commercialised, not necessarily on those generating most benefits to the public. The overhead on collaborative research, on the other hand encourages collaboration with Industry.

Other public sources: Since the benefits from knowledge transfer are mostly societal, it is legitimate for the national and/or regional governments to provide financial support to the operations of KTOs. Certain public sector organisations have begun to make available funds directed towards the IPR function. Examples of these include the EU programmes as well as regional and national government initiatives aimed at enhancing economic activity. In the UK for example, PROs are now entitled to bid for a third stream of funding known as the Knowledge Transfer Grant and this is awarded to institutions to support a broad range of KTO functions, from entrepreneurial education to supporting patent costs and commercialisation activities. With increased political focus on the need of a knowledge economy, it is hoped that such initiatives will spread to enable effective implementation of the innovation model. In the US there has even been legislation obliging national laboratories to dedicate 0.5% of their budgets for KTO functions.

Private Sector: As key stakeholders, both traditional industry and newcomers such as VCs are contributing to the innovation management process. By increasing levels of interaction with PROs and demonstrating to researchers that successful knowledge transfer is possible, there is an increase in access of PROs to early stage development funding as well as access to crucial expertise. Thus the KTO function is being indirectly supported.

Identifying and securing adequate funding is a challenge, which cannot be underestimated. However, it is the view of this group that since the KTO function is recognised as playing an essential role in knowledge economies, the matter should not be seen as one simply for the PROs to address. Public

sector stakeholders have a responsibility to support all the missions of their PROs, namely teaching, research and knowledge transfer.

6.5. Policies of the PRO

PROs need to equip themselves to manage a pro-active IPR management function by establishing key policies to assist both staff and external organisations to understand what the aspirations of the PRO are. It is essential that all stakeholders buy-in to the need for effective management of IPR. For the central administration of the PRO this means ensuring there are centrally developed and approved policies to provide the infrastructure of rules and procedures, which a KTO is charged to implement.

These include policies for all the relevant functions:

- managing ownership of inventions such that responsibility for IPR lies with the PRO;
- sharing net profits with inventors and their research units in order to encourage technology transfer;
- reviewing papers before publication in order to identify patentable inventions;
- assessing inventorship and ownership of inventions;
- negotiating collaborative research agreements;
- processing invention disclosures and filing patent applications;
- managing the patent portfolio;
- marketing the technologies available for licensing;
- have clear, robust and realistic licensing policies;
- provision of seed capital or information about seed capital;
- support to the creation of start-up companies;
- organisation and management of incubator facilities;
- coaching of spin-out companies;
- managing conflicts of interest

Many of these procedures may not initially be popular in a university environment and it may take time and much goodwill to make them effective.

6.6. Personnel Issues

The number of critical tasks to be adopted by and implemented within a university environment to enable the effective management of IPR is very large. This function requires five types of expertise:[37]

- a good command of all aspects of intellectual property law, patent law, anti-trust law, company law and contract law;
- a reasonable grasp of science;
- a good understanding of the various industry sectors and of the creation and governance of new companies;
- excellent project management and business development skills;
- critical negotiation and inter-personal skills.

It is essential that a combination of skills is available to KTO personnel, since there are many aspects to the effective management of IPR, from understanding legal rules to managing financial business

[37] A detailed analysis of skills and training needs can be found in the Oakland Innovation and Information Services report produced for the Department of Trade and Industry *Business Interface Training Provision (BITS) Review*, March 2002, info@oakland.co.uk

plans, from understanding detailed technical scientific experiments to appreciating the complexities of the international patent regime. The nature of IPR generated at PROs is generally remote from having immediate industrial application, while more specialist or applied research institutes may have more industrially applicable technologies arising from their research activities. It is important that the PRO puts in place appropriate resources to address the needs of the technology in question. A key role of the KTO is to ensure that the most suitable partner is found to take the technology on to the next stages of development e.g. if a proof-of-principle prototype has not been made yet and it requires further development work for which the PROs are not necessarily well equipped or even interested to carry out, then a partner is essential. This means that the IPR management also has a dimension of business development to identify the work, which may be required, and to find the best industrial partner. Such a relationship may take the form of collaborative research and development to demonstrate the proof-of-principle in exchange for licence rights. It may even be possible to secure venture funding for the development work, which can take place through the creation of PRO spinout companies.

Therefore the individuals who find themselves in the technology transfer environment will have come from a diverse background, from the laboratory to industry, from the legal world to that of the serial entrepreneur. A successful KTO must ensure that there is an appropriate induction to the perspectives of these topics. In this way, they will be enabled to interact effectively with all the stakeholders, be they inventors or representatives of a global multinational company. The most effective offices, as with any sector, are those where a strong leadership provides an open and shared vision of the aims of the KTO together with active demonstration of deal making.

Since most PRO's do not have the resources to offer salaries competitive with industry, there needs to be a strategic policy adopted by the senior management within each PRO to facilitate the attraction of well-qualified, effective people. It is essential that staff, once attracted, is given enough career and progression opportunities to wish to stay in the KTO environment. As well as salary considerations there are other aspects of employment, which can be enhanced in order to maintain effective staff, such as job satisfaction. If a KTO is perceived as being effective and adding value to the process of managing emerging technologies, then staff will be motivated to continue in that environment. It is essential therefore that the relationship with the research base is a good one, where a KTO is seen to add value to the aims of the institution, rather than being seen as a bureaucratic necessity. Top-down endorsement by senior management within the PRO is essential here.

It is essential that staff is clear about what the mission of the KTO is to be if conflicts of interest are to be avoided.

6.7. Networks of Interest

Active encouragement to network with other KTOs and technology managers from industry can help achieve several key goals.

There are many organisations, both formal and informal, around the world where individuals or organisations involved in managing intellectual property rights and engaged in technology transfer can meet and exchange views and experiences.

With particular reference to PRO's, much mention has been made of our US neighbours who formed a highly successful, professional support organisation called the Association of University Technology Managers (AUTM), which runs training conferences and seminars for staff of PRO's. In more recent years it has opened up associate membership for industrial and other non-PRO members. This facilitates an exchange of opinion and the development of best practices, which take into consideration the interests of a wide variety of stakeholders.

In Europe, several associations of KTOs have been organised at national level, including:

- UK: AURIL and UNICO
- France: Réseau C.U.R.I.E.
- Germany : Technologie Allianz
- Spain: Red OTRI
- Finland: Finnish Liaison Office
- Belgium (Wallonia): LIEU
- Italy: being formed
- The Netherlands: VSNU Liaison Group

There is a need for a relay on the dissemination of good practices at national level because the legal regimes of IPR, the systems and procedures for funding research and the cultures are different. The creation of national associations in the other countries should therefore be encouraged.

There are also several European associations active in exchanging good practices relevant to KTOs and providing training at European level, including:

- The Association of European Science and Technology Transfer Professionals (ASTP)
- The European Association for the Transfer of Technologies, Innovation and Industrial Information (TII)
- The European Association of Research Managers and Administrators (EARMA)
- The European Association of Research and Technology Organisations (EARTO)

Finally, the Directorate General Enterprise of the European Commission is funding the ambitious ProTon-Europe project, which is attempting to federate the national associations of KTOs at European level with the collaboration of the existing European associations. It is also funding the ITTE project (Improving Institutions for Technology Transfer from Science to Enterprise) which is currently making an inventory of all European transfer offices involved in the technology transfer process in order to help develop a benchmarking model and to give examples of good practices.

At world level, the oldest association of technology transfer professionals is the Licensing Executives Society (LES), which operates by way of national committees. Membership traditionally comprises IPR specialists such a lawyers and patent agents, but with the growth of economic activity around IPR in the last few years, there is now a much wider spectrum of membership and activity.

6.8. Benchmarking

As with any other function of PROs, there is likely be a requirement to assess or audit performance. If we look at traditional review mechanisms, we see that the audit aspect is to review the financial implications of the activity as well as to identify whether desired outcomes are being achieved. In reviewing the education remit, consideration is given to the standards of education achieved, numbers of students gaining qualifications, entering employment etc. A further function of review is to identify best practices and enable some form of benchmarking, so that PROs can direct resources at relevant training or adopting of good systems, which appear to work. Indeed, even this Report is an attempt to identify some best practices experienced across Europe and beyond in order to enhance effective IPR management in PROs.

As yet there are few formal review procedures established for this young profession although attempts to solve the resourcing dilemma have led some national authorities to seek to measure the potential returns from KTO activity. The single lesson that can be taken from these attempts is that any performance criteria must take account of all the objectives of the KTO. These include the benefits to society, economic impacts as well as direct financial returns. This complex challenge in the UK has

led to an initial proposal by the Higher Education Funding Council for data to be reported across some 250 metrics! Aside from the sheer volume of data that such a request would generate, there are significant issues about the source of such data, since the PRO is only one of the stakeholders in the innovation process. Initial data around numbers of patents, licences and new company formation can be readily found, but downstream impact measures about company performance and survival, taxation and infrastructure benefits are not readily identifiable. The discussion about performance criteria continues.

In the meantime, the KTO profession itself has begun to accumulate information from its members. Earliest reviews in the US about the success of the Bay-Dole legislation led AUTM to survey members and attempt to identify the benefits of their activities. The results tried to extrapolate the impact of technology transfer as far as identifying taxes generated and dependent employment figures. This proved to be too difficult to complete. Rather there is a need to collaborate with other stakeholders to build up a picture about how well the relevant missions have been achieved.

For PROs, benchmarking offers three critical functions. Firstly, it enables staff to identify training needs. Secondly, the exchange of best practices enables KTOs to manage problems that arise as a result of small critical mass. Staff can identify opportunities for improving efficiency by accessing a wider range of experiences and models. Thirdly it begins to pull together practices, trends and objectives that are shared and can perhaps be developed into a Code of Conduct which would enhance PRO abilities to fulfil their respective missions.

There are empirical reviews assessing the correlation between research activity levels and levels of technology transfer which serve as useful targets to identify a general level of activity. These are referred to in Chapter 1 above. The KTO is to provide a service and there needs to be some measure of what ought to be required to deliver the service.

More important, however, is the need to ensure that the expectations of the stakeholders, as reflected in the mission of the KTO, are transparent and accepted by all. Performance targets and measurements are only possible once there is agreement about the mission, agreement about the targets and agreement about the way to achieve these. The KTO function in Europe at present is embryonic and needs to be stimulated using all means available. The open discussion around objectives and benefits can only be enhanced by the co-operative, interactive environment that professional and political networks maintain. It is good to talk!

6.9. Conclusion

The experiences and experimentation of KTOs over the past twenty years as they have tried to engage successfully in the knowledge transfer process have identified that what is needed for Europe is the Innovation Model described here, which if implemented alongside the Open Science Model, will have a significant impact on the socio-economic well-being of Europe. By doing so, it will demonstrate to all the stakeholders that continued investment in PROs in essential. Policy lessons can be drawn from these experiences and are reflected in the Executive Summary.

USEFUL REFERENCES FOR KTOs

AURIL *Handbook of Intellectual Property Management*, http://www.patent.gov.uk/about/notices/ipguide.pdf

AURIL/UUK/Patent Office: *Managing Intellectual Property – A guide to strategic decision-making in Universities*, September 26, 2002, http://www.patent.gov.uk/about/notices/manip/index.htm

AUTM: *Technology Transfer Practice Manual*, revised 2003 edition, available from http://www.autm.net/index_ie.html

BBSRC: *Bioscience Exploitation Guide*. http://www.bbsrc.ac.uk/biobusiness_guide

IPR HelpDesk: http://www.ipr-helpdesk.org

European Commission

EUR 20915 - Expert group report – Management of Intellectual Property in Publicly-funded Research Organisations: Towards European Guidelines

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Public research organisations (PROs) have always been an important source of innovation. The report reviews the knowledge transfer processes and their evolution over the last 30 years. The processes evolved from an “Open Science” model in which the PROs did not retain any IPR, to a “Licensing Model” in which the PROs started to retain, protect and commercialise inventions based on their discoveries, essentially through licensing the IPR to industry or to start-up companies. However, over the last ten years, a third model, which we call the “Innovation Model”, has started to develop in Europe and to a lesser extent in the USA. In this model, the Licensing Model, which is still important, has been supplemented by a more active policy of collaborative research with industry, and by a pro-active involvement in the creation of spinout companies. The results are comparatively more important at regional level and have been encouraging so far in the countries where it has been applied to a significant level.

This report reviews the practical issues in defining the objectives, the missions, the functions, the funding and the resources and makes recommendations on how they can be resolved. Clearly, the job of knowledge transfer officer is particularly challenging and requires a very broad set of skills as well as exposure to industrial experience. It will inevitably take many years for a Knowledge Transfer Office (KTO) team to accumulate the skills, knowledge and experience for the job. This time can be shortened by supporting the development at European level of a professional association of KTOs in order to share experience, disseminate good practices and tools and provide continuous professional development and training.

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