

Intellectual Property Teaching Kit

IP Management



IP Management

Part of the IP Teaching Kit

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Introduction

Intellectual property reaches into everyone's daily lives. A basic awareness and understanding of IP is therefore essential for today's university students, who are the engineers, researchers, lawyers, politicians and managers of tomorrow.

It is vital that students become acquainted with elementary aspects of IP, so that they can benefit from it fully in whatever career they eventually pursue. Students and universities should be aware too of how they can utilise the incomparable wealth of technical and commercial information to be found in IP documentation, and understand the need for universities to convert their research into IP rights, manage their IP portfolios and engage in technology transfer to industrial partners for value creation and the benefit of society as a whole.

Last but not least, students and universities should be aware of the consequences of failing to protect IP assets correctly, including the risk of reverse engineering, blatant copying and even industrial espionage.

This is where the IP Teaching Kit (IPTK) comes in. Produced by the European Patent Office (EPO) in co-operation with the European Union Intellectual Property Office (EUIPO), the IPTK is a collection of materials – including PowerPoint slides, speaking notes and background information – which can be used to put together lectures and presentations on all kinds of IP, including patents, utility models, trade marks, copyright, designs and trade secrets. The materials can be tailored to the background of the students (science or engineering, business or law), their knowledge of the topic, the time available and their learning objectives.

IP Management is the last part of the kit, following on from IP Basics, IP Advanced and IP Search Tools. It contains the tools and information you need to deliver lectures on the main aspects of managing IP in a university context.

With the IPTK you have at your disposal an extensive set of freely accessible, professional teaching materials which represents one of the most comprehensive IP teaching resources in the world.

About IP Management

IP Management is part of the IPTK. It has been designed for teachers of students with little prior knowledge of managing IP rights, in order to provide them with teaching material about IP management, strategy and commercialisation. Lecturers may find it useful to invite a member of their university's technology transfer office (TTO) to give a short talk on the university's IP policy and the work of the TTO, and to answer participants' questions.

In addition to the main presentations, IP Management contains a case study which illustrates how a casual approach to IP management can lead to serious consequences in the commercialisation of IP.

IP Management consists of ready-made PowerPoint slides with speaking notes and additional background information. The speaking notes can be read out as they stand. The background information provides additional details which will help you prepare for the more advanced questions that students might have. It is not intended for this information to be included in the lecture.

For online access to the extensive IPTK collection, plus updates and further learning opportunities, go to www.epo.org/learning-events/materials/kit.html where you will also find a tutorial for teachers and lecturers.

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Slide 1

IP Management

Title slide



IP Management

Intellectual Property Teaching Kit

The focus of this presentation is on the practical aspects of managing IP.

Slide 2

General introduction

The focus of this presentation is on the practical aspects of managing IP.

There is a greater awareness among universities today of the need to protect the outputs of research programmes and to make the resulting IP available to businesses.

With this emphasis on protection and commercialisation, the question of how to manage IP is vital, not only for university technology transfer offices (TTOs) but also for small and medium-sized enterprises (SMEs), and industry engaging in R&D and collaborating with universities for access to IP complementary to their own research and development.

In terms of IP management, university staff and researchers must concentrate on developing and implementing “good practice” procedures for documenting, evaluating and controlling information on inventions, designs and other forms of IP. Clarifying and establishing the legal status of inventorship and ownership are also important due diligence questions that are central to the management of IP.

The aim of this presentation is to provide participants with an understanding of:

- the main steps in the management of IP
- policies and processes for managing their IP from the earliest stage of creation
- strategies for enhancing their IP portfolio and preparing it for commercialisation
- the steps required to manage and commercialise IP in an industry setting.

Participants will develop an awareness of IP management procedures and processes and learn about:

- practical tools and processes to help them capture, document and protect IP arising from their work
- the technology transfer options available for commercialisation of university IP
- the IP strategies adopted by companies to support their specific business models in commercialising new products and services
- ways of avoiding common pitfalls in managing IP.

GENERAL INTRODUCTION

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In the first part of this presentation I will introduce you to the most important aspects of managing IP as it applies to you.

In the second part I will explain important patenting strategies for IP developers and how companies use IP strategies to commercialise IP. You will find out about some "good practice" tools and procedures you can use to help you capture, document and protect IP arising from your work.

Finally, I will explain the steps taken by universities to transfer technology to industry, and how companies use IP commercially to support their business objectives.

I will finish on a practical note with an interesting case study which illustrates how a casual approach to IP management can lead to serious consequences in the commercialisation of IP.

Slide 3

IP management

This is the title slide for this section of the presentation.



The next few slides deal with the management of IP.

Slide 4

The four main pillars of IP management

Businesses creating new technology and business opportunities today usually include the sourcing of external IP in their development strategy, as well as engaging in both co-operative and in-house R&D.

Good practice procedures such as those already described for universities also apply to businesses. IPR support is usually provided by the legal department or external advisors.

The financial reward mechanisms for inventors in businesses are typically based on the legal requirements defined by national law. Depending on the commitment of the company's management to go beyond the fulfilment of the minimum legal requirements, further incentives might be offered. Inventors working for businesses most often obtain a lump sum payment with options for milestone payments, whereas universities usually share the revenues between the university, the institute on campus where the invention originates, and the inventors.

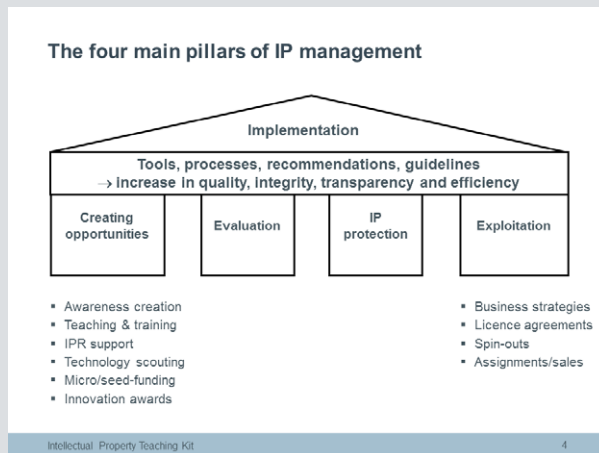
The goal of the evaluation stage is to identify highly attractive risk/reward profiles, so that resources can be focused on the most promising projects. Usually, this is done by an analysis of the legal, technical, financial and market aspects.

The objective of IP protection is to support the business case with the appropriate forms of IPRs. So it is important for it to be clear from the outset how the commercialisation is likely to happen, so that the relevant IP rights are secured. This is the daily business of TTOs, and normally researchers will obtain the corresponding support in making these commercial predictions and assumptions. The researchers then typically focus on preparation and qualification of the information required by the patent attorney who drafts the patent application.

Commercialisation agreements are usually put in place for each corresponding R&D collaboration. Know-how transfer, validation of the potential for further commercial applications and improvements to the technology are typical topics for inclusion in those

collaborative research agreements. So commercialisation activities also strengthen the business case of the university. And, as the commercialisation of a technology will generate a payback to the university, it clearly supports the business case of the TTO as well.

In practice, the outright assignment/sale of technologies does not arise that often at universities. One of the challenges for the negotiating parties is the differing perception of value at the time of a commercial transaction. The university often has unlimited expectations regarding the commercial opportunities, whereas the business, as the potential buyer, sees a mountain of risk ahead. If, for example, a valuation approach involving the discounted cash flow method were applied to calculate the value of the technology, a mutual understanding of the risks and opportunities and, consequently, the major cost and revenue drivers would be required. As technologies developed at universities are typically very early-stage, it is difficult to apply such valuation methods and it is often easier to simply agree on a risk-sharing model in the frame of a technology licence. This means that the income received by the university would increase in line with revenues received by the business from commercialisation of the technology.



The management of IP is based on four main pillars: creation, evaluation, protection and exploitation.

At universities, researchers are free to decide which kind of research they would like to pursue. So creating commercial opportunities in this environment usually means implementing activities that provide high-quality and well-qualified invention disclosures.

Let us start with awareness creation. It is essential that researchers be aware of the importance of technology commercialisation. They must also recognise that they can initiate and support the commercialisation process for the technology they have created.

Another component is teaching and training. Researchers and administrative staff should be

enabled to support the commercialisation in a meaningful way.

Faculties have to focus on research and teaching. In order to do so, they need IPR support from the university administration for setting up their collaboration contracts with third parties and funding agencies. These contracts need to include suitable IP rules that facilitate subsequent commercialisation.

Technology scouting is mostly done at universities with a very high commitment to innovation. At these universities TTO staff actively search for technologies with commercial potential. However, there may also be ad hoc external triggers, as technology brokers and companies implementing open innovation approach universities for solutions to commercially relevant problems.



Some universities offer micro- or seed-funding for technology refinement to increase the probability and potential of these technologies being commercialised.

If the commercialisation succeeds, inventors at universities are usually rewarded financially by receiving a share in the revenues. Some universities have innovation awards and organise inventors' days to publicly celebrate their inventors' success and achievements.

All these measures pursue one main goal, which is to increase the quantity and quality of the inventions disclosed to the technology transfer office.

In the next step, evaluation, it must be ensured that only the most promising projects are approved for IP protection. As resources are limited, it is essential to concentrate on selected cases and on the kind and level of IP protection that is required for commercialisation.

Protection ensures that the integrity of the IP is secured and prepares the ground for the exploitation stage.

Businesses usually focus on supporting their business strategy with the IP they protect, for example the products and services that they sell. Increasingly, the licensing of IP is becoming a part of their overall business strategy.

For universities, IPRs are also emerging as a business development tool which can be used to initiate additional collaborative research projects with licensees. In order to maximise the value creation for all parties involved, underused IPRs are licensed to third parties and/or may also establish the basis for spinning out companies. An alternative option for exploitation is to assign/sell the technology to a third party.

Implementation of the necessary tools, processes, recommendations and guidelines is required from the outset, to ensure the quality, transparency and efficiency of the overall IP management process.

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Implementing IP management

In terms of managing IP, the most critical stage in the creation of any form of IP is probably the development stage. This is where innovative discoveries and creations are made. If the conditions in place during the creation or maintenance of the IP do not meet the underlying legal requirements for that right, then there may be a real concern about whether a valid right to the IP exists or not. And in certain circumstances, once an error occurs, it can rarely be corrected easily.

What is crucial is that creative developments should be carefully and accurately documented. This is relatively straightforward provided some “good practice” procedures are implemented in the workplace. Today there are tools, processes and recommendations that are widely used to ensure that the correct procedures are followed.

University IP policies typically contain general recommendations for managing IP and lay out the benefits arising from research and creative work on campus.

Implementing IP management

- Tools and processes → assistance from technology transfer office
- Recommendations and guidelines → university IP policy

So what does IP management involve for academic researchers?

The first thing to consider are the tools and processes. Careful and accurate documentation of creative developments is essential, and there are a number of "good practice" procedures for researchers that can be put in place to help this process.

Support can be obtained from the technology transfer office – or TTO – on campus. They will be happy to advise and assist you with implementing good practices in the workplace. They might also be able to provide you with useful document templates.

Last but not least, you should find out about the university's IP policy. If you are involved in the creation of IP you need to be familiar with the main rules, guidelines and recommendations.

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IP policies at universities

University IP policies set out the university's objectives with respect to furthering innovation and should outline its role in disseminating the results of innovation programmes for the benefit of the university, business and society.

If IP is poorly managed and not correctly protected, IP rights may not be very useful to anyone. University IP policies therefore typically contain guidelines on how university IP should be guarded and managed.

Those aspects that need to be addressed all relate to the early-stage creation of IP. They are outlined briefly here and will also be explained in greater detail in the following slides.

The first aspect is the need for researchers to use a reliable method to record innovative concepts and results.

The confidentiality of the results is extremely important, which is why processes for guarding proprietary information are so necessary.

Intellectual property rights are legally determined rights, and it follows that anyone entitled to these rights must conform to the underlying legal requirements. The inventorship and ownership of the IP must therefore be carefully evaluated and correctly determined. Most universities will clarify in their policy that ownership of the IP arising from its employees' work belongs to the university. However, there are exceptions to this rule in some countries, so it is essential to know which rule applies at your own university.

The publication of research results in peer-reviewed journals is of course a requirement of most academic employees of a university and plays a major role for both the advancement of knowledge as well as the individual's career progression. The policy will reinforce this, but it will also recommend that, where IP is concerned, caution must be exercised and that protection for the IP must be ensured prior to publication.

For the university to protect and manage IP, it must first have a reporting process in place to enable its capture and evaluation. The policy will normally recommend, therefore, that all creations should be reported to the TTO on a standard form for review and evaluation.

Finally, most research and innovation programmes rely on collaboration between researchers in other universities and research centres. It is important to be aware of the rights of these collaborating partners and to ensure that these are not overlooked when determining inventorship and ownership.

IP policies at universities

- Recording of inventive concepts and results
- Preserving confidentiality of information
- Determining inventorship and ownership
- Publications
- Reporting of inventions
- Assessing third-party rights
- Reward system

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You should be familiar with the university's IP policy, as it covers a number of important aspects.

Such policies usually include using a reliable method to record innovative concepts and results.

The confidentiality of results is extremely important, so processes and tools for guarding proprietary information are necessary.

Inventorship and ownership must be carefully evaluated and correctly determined. In most countries, universities own or can claim ownership of the IP arising from their employees' work. Students, on the other hand, who do not have a contractual relationship with the university, most often own the IP they create.

The publication of research results is important for both the advancement of knowledge as well

as for individual career progression. But, where IP is concerned, you must exercise caution and you should ensure that protection for the IP is in place before it is published.

Processes for capturing and evaluating IP are very important. All creations with a potential impact on society should be reported to the TTO on a standard form for review and evaluation.

You also need to be aware of the rights of collaborating partners and to ensure that these are not overlooked when determining inventorship and ownership.

Finally, under the university's IP policy the revenues generated in the course of the commercialisation are split in a defined ratio between the university administration, the research unit and the inventors.

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Tools and processes

Confidentiality

Should inventors or creators need to disclose their work to third parties (other people not involved in the work), they will need to consider whether they want to keep it confidential. If so, they should have the recipients sign a non-disclosure or confidentiality agreement (NDA or CDA). This is simply a “good practice” procedure for exchanging information in a professional capacity, and there is no need to feel uncomfortable about requesting this, even if the other party is a former colleague or friend.

You might ask if these agreements are actually of any benefit, as an NDA of itself is not going to prevent misuse of information. This is true, as NDAs only come into effect when a breach of obligations has taken place. Nonetheless, the process of completing it does have a proactive effect in that the other party is more likely to reflect on the obligations and duty of care expected in not disclosing the information to others. On the other hand, if there is no NDA, the recipient of the information may genuinely not have any appreciation that there was an expectation of confidentiality.

IP capture

It is a long tradition in scientific research to record all project plans, experiments and results in a laboratory notebook. But this practice should not be confined to scientific research. Anyone involved in performing innovative and creative work should keep a notebook, work journal, design mock-ups, storyboards, etc. to record the work they do on a daily basis. This is where the IP that underpins the invention or creation is captured. As is evident from the case study that we will look at, this is an essential source of evidence which may be required to resolve disputes surrounding the inventorship and ownership of IP.

Reporting IP

IP created at a university should be reported or disclosed in accordance with the university’s IP policy. Normally it will be reported to the technology transfer office, which will initiate a review of its commercial potential and decide what form of IP protection is required. The invention disclosure form used for this process contains a fairly standard set of questions. Everyone should be familiar with this form and the review process.

Protecting IP

The next element in managing IP is ensuring that it is protected in line with the relevant legal requirements, registration processes and commercialisation strategy.

Not every piece of creative work will lead to an invention, so the appropriate form of protection – e.g. patent, design right, database right, copyright, etc. – will depend on the specific nature of the innovation. An introduction to the different forms of IP can be found in the IP Basics and IP Advanced modules of the IP Teaching Kit. Usually, staff at the TTO can provide advice on what form of protection is suitable and how to go about obtaining it.

Tools and processes

▪ Confidentiality	→	Non-disclosure agreements
▪ Capture	→	Lab notebooks/work journals
▪ Reporting	→	Invention disclosures
▪ Protection	→	IPR (patent, design, copyright...)
▪ Collaborations	→	IP provisions in contracts

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When managing IP arising from a research programme or piece of creative work, the focus must be on the ability to keep it confidential, the method of capturing it, the process of reporting it for evaluation and the form of protection it requires.

If you need to disclose work to third parties – other people not involved in the work – the first thing to do is to decide whether you need to keep it confidential. If so, ask the recipient to sign a non-disclosure or confidentiality agreement. This is simply a "good practice" procedure for exchanging information in a professional capacity.

You should also keep a notebook, work journal, design mock-ups, storyboards, and so on, to record the work you do on a daily basis.

IP created at a university should be reported or disclosed in accordance with the IP policy, so that it can be reviewed for commercial

potential and protection where appropriate.

The invention disclosure form used for this contains a standard set of questions to assist the process.

Not every creation will result in an invention, so the appropriate form of protection depends on the specific nature of the innovation, in other words whether it is a patent, design right, database right, copyright, and so on.

The technology transfer experts will provide advice on the form of protection required and how to manage the process. Together with the legal department, they will also advise on what provisions should be in the contract if the research is done in collaboration with external partners.

Slide 8

Notebooks and work journals

Maintaining a daily log of research experiments and creative developments can be of great benefit. It means that, at any point in the future, you can refer back to work you completed, review the specific details and then repeat or modify them for some other project you wish to work on. Adopting a work practice like this is also an excellent start in the process of managing IP.

Although you may use the notebook for your own benefit, situations may occur when third parties need to review the entries corresponding to work you have completed. The following points will highlight situations where such information is required, so you should bear this in mind when recording details, and ensure they are clear and legible.

There are generally accepted guidelines for how laboratory notebooks and work journals should be used and maintained and it is worthwhile asking your TTO for more information. If it complies with the accepted guidelines, then any information cited in the notebook will be accepted as valid evidence in situations where it is required.

Patent applications

The notebook is a source of key results and raw data that can help with the drafting of a patent application. The experiments recorded can be used to describe how an invention works, and the results will help construct the most appropriate set of claims.

Inventorship and ownership

Where several people have worked together on a project, uncertainties or even disputes may arise regarding who the inventors on a patent should be, particularly in multi-centre collaborative projects such as those funded under EU Framework Programmes. Notebook entries are a valuable source of clarity in deciding which parties contributed to the concept of the invention. This topic will be addressed in detail in the case study to follow.

Regulatory purposes

When products are submitted for regulatory approval, it may be necessary to show that the experimental protocol and data collection methods were performed in accordance with the regulatory requirements. This is

particularly so for life science inventions. The notebook is an important fall-back for verifying the procedures used in gathering the experimental data.

Contractual obligations

Grants and funding programmes may stipulate that all experiments and results are recorded in accordance with standard notebook procedures. By adopting this procedure the recipient of the funds can verify that this legal obligation is being met.

Know-how

Most technology licences will stipulate that the rights granted are to patents and the associated know-how. Investors in university spin-outs will also insist on a transfer of all relevant know-how. This makes access to the source of the know-how an essential reference point for the licensee and investors, who will want assurances that a good record has been kept of the original research results and experiments relevant to the patent and know-how. The laboratory notebook can be that source.

Notebooks and work journals

- "Good practice" record of research or creative work
- Critical to addressing many concerns, including:
 - data to support patent applications
 - inventorship and ownership
 - data and procedures for regulatory purposes
 - contractual obligations
 - know-how relating to licence deals and IP assets of spin-outs

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The notebook is an important source of key results and raw data which can be used as a starting point to draft a patent application.

Where a group of people are working together on a project, notebook entries are a valuable resource in deciding which of them are the inventors, and to what extent.

When products are submitted for regulatory approval, entries can be used to verify that the experimental protocol and data collection methods were performed in accordance with the regulatory requirements.

Funding programmes may include a contractual obligation that the research is recorded in accordance with standard notebook procedures.

When licences are granted for patents and the associated know-how, the licensee will

expect to have access to a record of the original research results and relevant experiments.

The initial value of most early-stage university spin-outs can be found in their intellectual assets. Notebooks can play a significant role in verifying a company's assets. Investors and purchasers will therefore seek assurances that they are available and have been properly maintained.

Slide 9

The invention disclosure form (animated slide)

IP created at a university should be reported or disclosed to the technology transfer team (if recommended in the IP policy), who will initiate a review of the commercial potential and decide what form of IP protection is required. The invention disclosure form (IDF) used for this process contains a fairly standard set of questions and everyone should familiarise themselves with this form and the review process.

Most university IP policies recommend that inventions be disclosed to the TTO in a timely manner, so that they can be evaluated for commercial potential and decisions on the appropriate form of IP protection can be made in advance of any submissions for publication. This is to the benefit of all involved, as the sooner decisions are made with respect to the protection and commercialisation of new technologies, the easier it will be to bring these to businesses and derive economic benefit from them. Also, the evaluation process will help you to decide whether to submit a publication (see next slide).

The invention disclosure form

- Important document for universities and inventors
- Information requested is designed to help:
 - evaluate patentability and commercial potential
 - determine inventorship and ownership
 - assess possible third-party rights
 - provide information for patent attorneys (inventive step and novelty)

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As we have already seen, any IP created at a university should be reported to the technology transfer office. To do this, you should use an invention disclosure form, which contains a fairly standard set of questions.

The commercial relevance of the invention is the most important and also the most difficult question, as it will not make any sense to patent an invention if there is no potential for value creation. So the form will ask specific questions that will help evaluate this. The patentability of the invention will also be assessed.

Inventorship on a patent is a legal requirement, so it is very important to determine who the inventors are. Ownership of the patent will stem from the inventorship. In most European countries, employees who create inventions during the course of their work assign any patents and other IP to their employers. In our case, this would be the university. However,

there may be exceptions to this. For example, in Italy and Sweden, inventors at universities have special ownership rights. So parties involved in transnational collaborative projects need to know if the laws are different for any of the partner countries.

Any assistance, information, software or materials provided by third parties needs to be fully declared, as these may have some bearing on the inventorship, and ultimately the ownership, of the patent.

The invention disclosure form captures information about the invention itself, including the inventive step and novelty. This will help the patent attorney evaluate the patentability of the invention and draft a patent application.

Slide 10

Proprietary information (animated slide)

Publication in peer-reviewed journals plays a vital role in academic life, and in an individual's career. Procedures for managing IP must acknowledge this, and balance the protection and control of IP against the requirement to publish. Technology transfer office staff use the information provided on the invention disclosure form to decide how best to proceed. They can usually review draft papers, assess them for any content that may be relevant to a possible patent application and propose possible edits that would avoid public disclosure of the invention.

Caution is also recommended when exchanging information with third parties outside the university, for example companies or other research groups. Such disclosures might affect the patentability of any inventions relating to the information discussed or disclosed, so it is vital that the recipients of the information sign a non-disclosure agreement, or NDA. Researchers should be particularly cautious if recipients are working on a similar project that could feasibly lead to a similar invention. Once the information is disclosed, there is the possibility of "contamination", which would cloud the real origin of any subsequent invention. In such cases, experts recommend discussions on non-confidential exchanges first to assess if this might be a possibility.

If you plan to provide or receive materials for use in a research project, you should make sure that you sign a material transfer agreement. This sets out the terms and conditions for use of the material. This is important, as some of the terms may impose certain restrictions on publishing and protecting the results of the project, or even on ownership of new materials and inventions arising from use of the material. If the terms for receipt of the material are too onerous or would constrain the scope of their research then the recipient may need to consider declining the material.

Proprietary information

- Take advice on the timing of your publication
 - Does it contain information relevant to a patent application?
 - Will it be published before a patent application is filed?
 - Should you withhold certain information?
- Take precautions regarding disclosure and receipt of confidential information and materials
 - Disclosure or receipt of information → non-disclosure agreement
 - Material transfers → material transfer agreement

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If you think there may be some potential for value creation in your research findings, it is a good idea – and sometimes even a legal requirement – to talk to the technology transfer office before you submit a paper to a journal or make any other commitment to publish.

If you have already prepared a draft paper, it can be reviewed by the TTO and assessed for any content that may be relevant to a proposed patent application. The office can suggest edits to the paper that may avoid public disclosure of the invention and thus still allow a patent application to be filed. Best practice of course is to file the patent application prior to making any other form of publication.

Before you exchange any critical information with third parties such as companies or other research groups, you should always ask the recipients of the information to sign a non-disclosure agreement. Without this, the

patentability of any inventions relating to the information being discussed or disclosed might be seriously affected.

You should be particularly cautious if you suspect that the recipients are working on a similar invention, as there will be "contamination" of information once it has been disclosed. In this regard, it may also be better to avoid receiving information from them, or anyone else working on a similar invention.

If you plan to exchange materials for research purposes, it is best to sign a material transfer agreement first. This allows you to control the use of your material under specific terms and conditions. Again, the technology transfer office and the legal department can advise on this and on any precautions that should be taken.

Slide 11

Collaborations (animated slide)

Another area where careful management of IP is required is in any form of collaborative activity, whether in scientific research, prototype development in an engineering field, software development or design and creative developments in the visual and performing arts.

Most of the difficulties and disputes that arise in relation to IP in the university environment usually originate from collaborative work. Here parties are brainstorming and pooling their creative contributions to solve problems. If the contributions from each party are not correctly recorded and acknowledged, problems emerge in determining the correct inventorship and ownership of the IP that underpins the invention, design or creative work.

The first point to agree is how the project IP will be defined. There may be some IP that parties bring to the table which they own. This is usually declared and recorded as background IP. Results arising from the project will fall within foreground IP. Some of this foreground IP may be jointly owned and called joint IP. Some parties may create IP in parallel and outside the project, which is then brought into the project and referred to as sideground IP. There may be improvements made to the foreground IP after the project has been completed and these may need to be defined. For each form of IP associated with the project, the parties need to ensure that they have defined it clearly and included provisions for ownership, access to it by other parties, and rights to use and commercialise it.

Finally, large collaborative projects that are funded by government or EU research programmes usually have industry partners involved, and these parties will have specific interests in access to the project IP and the rights to commercialise it. Universities may also wish to have specific access rights to retain certain elements of the IP for use in their own research and in further collaborations. Filing and commercialising patents can be an expensive business, and money is invested with a view to corresponding returns. The parties need to agree upfront on sharing of costs, risks and returns. All of these interests need to be aligned (negotiated) and provisions included in the legal agreement for fair and equitable duties and rights for all parties.

Collaborations

- Definitions of IP used and created in the project
- How it will be managed
- Ownership and access rights
- Ownership and access to improvements to IP
- Who will file and prosecute patents
- Sharing of costs, risks and returns
- Terms for publications

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Before any collaborative project begins, the parties should agree on the important items they wish to control in the work and in the outputs from that work. These items should then be set out in a collaborative agreement, which should include terms for management of the IP.

The first point to agree is how the project IP will be defined. There will be different forms of IP associated with the project – background, foreground, sideground, joint IP and improvements – and the parties need to ensure that each has been clearly defined.

The size of the project will determine whether one person or a committee is appointed to manage the IP. This will include recording, reporting, evaluation, protection and commercialisation.

The agreement must also contain provisions for the ownership of inventions and access rights to the project IP, as well as the rights to use the IP

for further research and for commercialisation of the IP.

After the project has been completed, parties may make improvements to the project IP, so they need to decide if access rights will extend to these improvements and, if so, under what terms.

Commercial evaluation and patent protection are important aspects of IP management. The parties should agree who will file, prosecute and maintain any patent applications.

Filing and commercialising patents can be an expensive business. The parties need to agree upfront on how they want to share the costs, risks and returns.

The academic parties will almost definitely want to publish the results of the project, so the protocol for reviewing and submitting publications needs to be agreed on, in order to avoid conflict with the commercial interests in the project.

Slide 12

IP strategy

This is the title slide for this section of the presentation.

IP STRATEGY

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In this section we will look at some of the main strategies relating to the development and protection of IP. We will then examine how companies use IP strategies to commercialise IP based on their own specific business models.

Slide 13

IP strategies for universities and businesses (animated slide)

Apart from the professional inventor whose objective is to create new inventions and then consider the feasibility of patenting and commercialising them, most IP developed in the workplace is a consequence of the specific mission or goals of the organisation. But, in general, the creation of IP is not the primary objective of most organisations and businesses.

Universities have a specific mission that involves teaching, furthering knowledge through fundamental and applied research, and disseminating knowledge to benefit communities and society. Part of this knowledge dissemination, which includes IP, takes place through technology transfer to the business community. Collaborative research, licensing and spin-off formation are just part of the overall technology transfer spectrum.

Businesses set out their goals in a business strategy and determine the achievement of these goals by means of a business plan. A company's business objective may be to develop, manufacture and sell a certain kind of product and/or service for a specific market, or it may generate its income from commercialising a widely used technology through licensing and sale of its IP. It can be both, a user and a broker of its own IP, and therefore relies on it to support and protect its revenue-earning activities.

Universities and businesses are fundamentally different kinds of organisation, so their IP strategy may vary depending on their specific needs and objectives. Although IP may be a subsidiary element in terms of their main objectives, it does play a direct part in achieving their goals. It is therefore important that, whatever business strategy they each develop, it must include a well-defined IP strategy as an integral part of that overall strategy.

IP strategies for universities and businesses

- Universities
 - teaching
 - fundamental and applied research
 - technology transfer (i.e. no in-house production and sales)
- Businesses
 - own development, manufacturing and/or sales of products and services
 - commercialisation of technologies (out-licensing, IP sales)

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Universities and businesses are fundamentally different types of organisation, with completely different sets of activities and objectives which affect their approach to IP strategy.

Universities are clearly focused on teaching and learning, furthering knowledge through fundamental and applied research, and disseminating this knowledge to benefit communities and society. They have no production or sales activities and in this sense they are not the main users of IP.

The more commercially relevant part of these knowledge dissemination activities, which relates to the creation and commercialisation of the university's IP, involves the transfer of knowledge via technology transfer to the business community.

Businesses, meanwhile, tend to concentrate on developing, manufacturing and/or selling

a certain kind of product or service for a specific market, or on generating income from commercialising a widely used technology by means of licensing and selling their IP. They can therefore be both users and brokers of their own IP.

IP is vital to both universities and businesses in that it plays a part in helping them achieve their mission or business goals. So whatever overall business strategy they each develop, a well-defined IP strategy will be an integral part of it.

Slide 14

IP strategy approaches (animated slide)

IP strategy approaches

- Developing and protecting IP
 - particularly relevant to university activities
 - also relevant to businesses
- Creating a competitive advantage by optimising and using IP
 - relevant to university spin-out companies
 - relevant to businesses

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IP strategy may be viewed from two perspectives.

In one, the focus is on the process of developing IP and deciding on the appropriate protection strategy. For early-stage IP, this is where most of a university's activities lie and where it usually focuses its decisions and strategy.

Businesses that are active in research and development programmes also have an interest in determining the appropriate strategies for their company on this front.

The second focus is directed at all the functions and objectives relating to the commercial application of the IP for creating a competitive advantage. The commercial world determines the specific IP strategy required to engage in a particular business sector or market, and this is very much focussed on optimising IP for specific business uses and objectives.

This aspect of IP strategy will be the remit of university spin-outs and new technology start-ups, as well as businesses already competing in the marketplace.

Universities usually do have a commercial strategy for out-licensing and divesting themselves of their IP, but it is different to that of businesses, as they do not directly engage in the development, manufacturing or selling of products and services.

Slide 15

Developing and protecting IP

In developing and protecting IP there are a number of strategic objectives to be considered, as well as tactics for meeting these objectives.

“Monopoly” and proprietary rights

The first is to decide whether you wish to create a “monopoly” position for your technology. There are three main options here, depending on your strategic needs:

- The innovative findings can be published and made available to everyone, thereby preventing anyone from having a “monopoly” on the technology and related products. In the case of software, this also could mean that the software is published under one of the licensing systems for open source software.
- Alternatively, if you have a keen commercial need you can decide to protect the technology with a patent, thereby creating a “monopoly” for the owner.
- Thirdly, you may decide not to file for patent protection. Companies often take this option either because they feel a strong patent may not be granted, or because they do not want the workings of the invention to be publicly disclosed in a patent specification which others might copy. They decide instead to maintain the technology as secret know-how.

At first sight, the options seem to contradict one another, but in practice, it is possible to actually combine all three approaches, as products often rely on combined IPRs having different functions in the overall commercialisation strategy.

Patent filing strategy

Most universities will follow a “cost-delaying” strategy, making use of the priority year and extending this by filing their patent applications under the EPC and/or PCT system. The national phase can be postponed by up to 30 (PCT) or 31 (EPC) months after the priority filing. This has the benefit of avoiding the main patent fees until much later in the process and allows time for the university to commercially evaluate the invention and search for a potential licensee or buyer. If there is no success in commercialising the invention, the university may abandon the application to avoid further costs.

If the university proceeds into the national phase, it must have a strategy as to where it will protect the invention. Countries must be chosen for further prosecution. This decision will depend on the commercial relevance of the technology or product.

Portfolio creation

To increase the chances of commercialising a technology, patent holders should consider how to enhance the status of the initial invention and make it a more commercially attractive proposition. For example, this could mean expanding the research programme to develop further applications of the technology or complementary technologies. All this will assist in building a portfolio of patents related to the field of application. The strategy, therefore, is to create a valuable IP portfolio that ring-fences a “monopoly” position in a particular field of commercial interest. This may extend to including protection for other valuable forms of IP such as design rights, trade marks and copyright.

Developing and protecting IP

Strategic objective	Tactic
"Monopolising" the technology	<ul style="list-style-type: none">– Publish and ensure wide access, or– Protect with patents and other IP forms, or– Maintain as secret know-how
Managing the IP filing strategy	<ul style="list-style-type: none">– Maintain application for a limited duration– Decide which territories should be protected
Enhancing the status of the technology	<ul style="list-style-type: none">– Develop complementary technologies– Create portfolio of related patents & other IP

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When developing and protecting IP there are a number of strategic objectives you should consider.

Firstly, you should decide whether you wish to “monopolise” or allow free access to your technology. There are three options here. One is to publish and make the technology available to everyone. This prevents anyone from having a monopoly. Wider application of the technology stimulates further innovation and hopefully further improvements to it for the benefit of everyone. The second objective is to protect the technology with patents and other forms of IP. This might create a “monopoly” for the owner, as a patent grants the right to exclude others from using the protected technology. The third is to maintain the technology as secret know-how, either because a strong patent may not be granted, or because you do not want the workings of the invention to be publicly disclosed for others to copy.

Universities may have a strategy to maintain a patent application for a limited period only. If they cannot find a licensee, they may abandon the application to avoid further costs. They must also have a strategy regarding where they want to protect the invention in geographical terms. Which countries they choose will depend on the commercial relevance of the technology.

Patent owners should consider how to enhance the status of the initial invention by making it a more commercially attractive opportunity. This could mean, for example, carrying out additional research to develop further applications of the technology, or technologies that complement it. The strategy is to create a valuable IP portfolio that ring-fences the products and services in a field of commercial interest and that may also include other valuable forms of IP protection.

Slide 16

Creating a competitive advantage

A business's IP strategy will be led by its commercial objectives and business plan. Whether the source of the income is a technology, a product, a process or a service, the company will need to identify key IP it uses in all areas of the business and ensure that it has the appropriate form of protection in place, including patents, design rights, trade marks, copyright and database rights. Securing other important property that it relies on to carry out its business, such as know-how, trade secrets and domain names, will also be very relevant. The strategy should focus on optimising these IPRs for the best possible advantage in the marketplace.

Creating a “monopoly”

In deciding on how best to create a “monopoly”, a company will have to consider whether it should keep certain information secret or use it to obtain patents. It is very much a strategic decision on what will work best for the business. In making these decisions it needs to have a good overview of the IP landscape in the technology field and markets in which it is active. This means knowing what IP competitors already have and what new technologies are being developed. It should also take professional advice (from patent and IP attorneys) on whether its own products and technologies are free from infringement of any of the patents it has identified in its prior art searches (freedom-to-operate or infringement clearance).

When a company has invested in building an IP portfolio, its IP strategy should then include processes for the enforcement of its IP. This will involve monitoring competitor activity and notifying infringers of its IP status. The strategy should include non-adversarial approaches to resolving infringement disputes such as mediation and licensing, as going to court is often expensive, risky and time-consuming for all parties involved.

Competitors

IP strategies normally also include the option of using a patent portfolio as a competitive tool. Here certain patents may be strategically filed to prevent competitors from gaining the upper hand in specific technological fields. This is a defensive strategy and may go hand-in-hand with a cross-licensing strategy, where risk is mitigated by offering competitors a licence to these patents in return for

a licence to the competitors' patents that it is in danger of infringing.

Investment

For many university spin-out companies and new technology start-ups, investment from private investors or venture capital companies is the only means of bridging the gap in the initial pre-revenue years. The IP strategy for these companies includes building an attractive patent portfolio as a pool of valuable assets that can be offered as collateral against investment.

Monetisation

All the methods used to create value or generate revenues from commercial transactions involving IP fall under monetisation. In the next part of this presentation, we will look at the different options available for commercialising IP. However, for completion of the discussion on IP strategy, it is appropriate to mention how important it can be for a company's revenue-earning activities to include a strategy for monetising its IP. This may involve several options, such as out-licensing, outright sale, co-development of IP for clients, or perhaps creation of a new business entity (spin-out) to capture value in its IP.

Open innovation (sourcing IP)

As part of its IP strategy, every company should consider how best to improve and enhance the status of its IP portfolio. Depending on the availability of in-house resources and expertise, it may not be possible to achieve certain technology and IP objectives, so it might be necessary to source these outside. A good open innovation strategy will involve collaborating with companies and universities to undertake research on projects it cannot complete in-house and to negotiate access to new technologies and IP through acquisitions and licensing. This will allow the company to build its IP portfolio in areas where it has gaps and maintain its competitive advantage.

Creating a competitive advantage	
Strategic objective	Tactic
Creating a "monopoly"	<ul style="list-style-type: none"> – Be aware of IP landscape (competitors) – Ensure freedom-to-operate – Police infringers – Defend "monopoly"
Managing competitors	<ul style="list-style-type: none"> – Create defensive patents – Trade IP for cross-licensing deals
Securing finance	<ul style="list-style-type: none"> – Build IP portfolio to attract investment
Monetising the IP portfolio	<ul style="list-style-type: none"> – Consider out-licensing, sale of IP, spin-outs
Sourcing new IP	<ul style="list-style-type: none"> – Use collaborations, in-licensing, acquisitions

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Any company wanting to create a kind of “monopoly” needs a good overview of the IP landscape in the technological field and markets where it is active. It needs to know what IP competitors have and what is being developed. It also needs professional expertise and advice on whether its own products and technologies are free from infringement.

A typical IP strategy should also include processes for enforcing the company's IP, such as monitoring competitor activity and notifying infringers of its IP status. Methods for resolving infringement disputes could include mediation and licensing.

A business that uses patent portfolios as a competitive tool can prevent competitors from gaining the upper hand. This is a defensive strategy that the business can apply together with a cross-licensing strategy to mitigate the risk of infringement. It involves offering competitors licences to the business's own patents in return for licences to the competitors' patents.

In terms of securing finance, many university spin-outs and new technology start-ups focus on building an attractive patent portfolio as a pool of valuable assets that can be offered as collateral against investment.

Revenue-earning activities may include a strategy for monetising a business's IP. This may involve a number of options, including out-licensing, outright sale, co-development of IP, or perhaps the creation of a new business entity or spin-out to capture the value in the IP.

To maintain its competitive advantage, a company may also need to build its IP portfolio in areas where it has gaps. An open innovation strategy that involves collaborating with other companies and public research organisations that undertake research it cannot complete in-house can provide access to new technologies and IP by means of acquisitions and licensing.

Slide 17

Commercialisation of IP

This is the title slide for this section of the presentation.

COMMERCIALISATION OF IP

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In the previous section we spoke about strategies for enhancing and creating value in IP portfolios. This next section looks at the different ways that universities and companies leverage their IP to create commercial opportunities.

There are many ways to extract value from an IP portfolio. Technology transfer is the means by which universities ensure that their IP is used to the benefit of the business community, to which it is transferred for a wide variety of commercial applications.

Companies may use their IP to support their own product development and manufacturing activities as their prime objective, or they may also have a strategy to generate additional revenue from it. Both of these possibilities will be examined.

Creating value in IP for the purposes of investment is an important objective of university spin-outs and new technology start-ups, and the section will conclude on this topic.

Monetisation was mentioned in the previous slides. Licensing is a common approach to commercialising IP and this legal concept will be explained in this section with the benefits and risks associated with it.

Slide 18

Technology transfer

In the university sector, there are many ways in which IP derived from creative endeavour can be disseminated to the wider community. In some instances this may be for educational or academic purposes. In other cases it may be specifically for commercial applications. Broadly speaking, these activities come under the heading "technology transfer".

Collaborations

University partners may find it beneficial to retain IP developed in collaborations for use in further collaborations with both university and business partners.

Technology transfer

- University objective
 - to make innovative research results and technologies available for wider use by means of technology transfer
- Possibilities for technology transfer
 - publications, people and artefacts
 - collaborations
 - contract research
 - licensing
 - sale
 - spin-outs

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In the university sector, as well as in other publicly funded research organisations, new findings and advances in knowledge are disclosed for public access in publications, by people and in the form of artefacts. The standard method for disseminating is to publish in peer-reviewed journals and conference presentations, where information is made freely available for all to use, and in the form of the university's graduates, who go on to work in business. Investigations at universities also give rise to a variety of artefacts that are then made available for public and/or commercial use.

Collaboration between large groups of researchers at different organisations allows a critical mass of skills and resources to advance complex and fast evolving technologies. Such projects are typically funded by government and EU research programmes. The partners involved – many of them SMEs – can negotiate access to the resulting IP and use it for commercial purposes.

Contract research is a form of collaboration

where universities conduct a defined piece of research on behalf of a company. Often, a lump sum fee is paid for the transfer of the results, technology and IP to the company.

Licensing, which is the main activity of many university TTOs, enables commercially relevant IP to be transferred out to the business community. It will be explained in more detail later.

In another option, universities may not wish to retain ownership of a particular piece of IP and may offer to sell or assign ownership of it to a company for a lump sum payment.

Spin-out companies are often supported by campus incubation centres. Here, university IP is licensed or assigned to them in the initial phase of setting up the company. As the companies grow they attract investment and extract value from the original university IP. Eventually, they build on the IP, developing their own portfolio and moving away from the university campus as successful start-up companies.

Slide 19

How universities can exploit IP

The technology transfer office is often the hub of all commercial activity revolving around the management of university IP. The goal is to secure exploitation of technologies and IPRs by transfer to the wider community, which in most cases is the business community.

The schematic diagram on this slide illustrates the process involved. Evaluation is central to all activities in the process and is not a one-off activity. This ensures that, at each step of the way, those involved can continually review and update the status of the technology and associated IP, to ensure that it continues to make commercial sense and warrants the commitment, financing and resources required to transfer the technology.

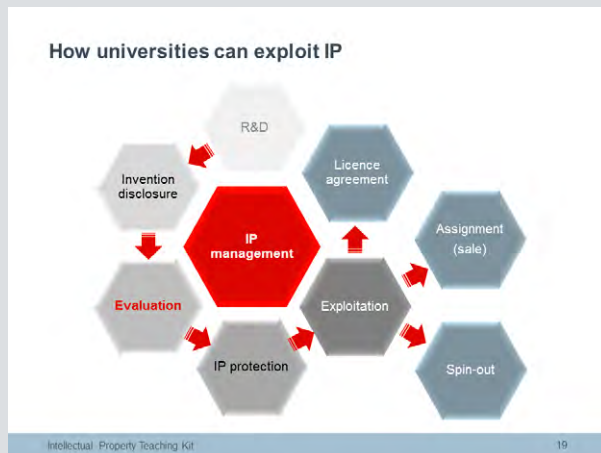
The process begins with the submission of an invention disclosure form, as explained earlier. At this point there is a full evaluation as discussed on the next slide. A positive outcome from the evaluation will lead to the filing of an application for the appropriate form of IP protection. A refinement of the technology may be required later to demonstrate that it clearly functions in a commercial application. This may involve the construction of prototypes, the completion of wider studies to show statistical relevance, or the improvement of software programmes or design configurations. After each of these stages a reaffirmation of the commercial relevance is necessary before proceeding further. Finally, partnering and negotiations for transfer of the technology to a business partner can commence. The commercial opportunities are mostly found with the SME community in the region of the university, but large companies are often interested in key technologies that complement their R&D programme and provide for new applications to their existing offers.

Commercial transactions for transfer of a technology may take different forms. For instance, in a typical licence negotiation, a TTO may decide to divide the technology into separate applications specific to different business and product sectors. A licence fee and/or royalty payment is negotiated and a licence is then granted to a company for a specific application of the technology relevant to the sector in which it operates.

Alternatively, a company may be interested in acquiring ownership of a specific patent held by a university, and if the TTO decides that the deal is good and there is no particularly reason to retain ownership of the IP, it may sell the IP outright on payment of a lump sum. In practice, sale agreements often include a performance or milestone component with a view to sharing the risks and opportunities.

Another option is to support the emergence of spin-out companies from the university and to allow a transfer of the technology into the new company under a licence or assignment of the associated IP. As the companies grow, they attract investment and extract value from the original IP and eventually move away from the university campus as successful start-up companies. The universities are rewarded by shares and/or licensing fees, as well as by collaborative research projects with the spin-out company.

A research group may have a vested interest in a particular technology for participation in collaborations, and may ask the TTO to reserve the technology, or specific applications of it, for such purposes.



This slide shows the processes involved in IP management. As you can see, exploitation options play a central role.

The process begins after R&D with the disclosure of an invention to the TTO.

Then a full evaluation is carried out of the technology, the potential for strong IP and the commercial opportunities. If the evaluation is positive, an application for the appropriate form of IP protection is filed.

Before the technology can be promoted to the business community, it may sometimes be necessary to carry out some refinements, for example to construct a prototype.

At each stage in the cycle, it is necessary to reaffirm the commercial relevance before proceeding further.

Eventually, the TTO will make the initial contact with the partners and commence negotiations for transfer of the technology to them. A licence may be granted to a company for a specific application of the technology relevant to the sector in which the company operates. Sometimes a company may be interested in acquiring ownership of a specific patent, and if the deal is good and there is no reason to retain ownership, the TTO may sell the IP outright.

Another option is to support the formation of university spin-out companies by staff members and to transfer technology into these companies under a licence or by way of assignment of the associated IP.

Slide 20

Evaluating IP

As already mentioned, the aim of IP evaluation is to identify attractive risk/potential profiles with a view to selecting the most promising projects. This is usually done by analysing the legal, technical and market aspects. Strategic and financial aspects need to be considered as well, but in the university environment these aspects tend to impinge on projects in specific cases only.

There are a number of tools available to help with the evaluation. The EPO's IPscore®, for example, is available free of charge at www.epo.org/searching/free/ip_score_de.html. IPscore uses around 40 questions to carry out a qualitative evaluation and ranking of the technologies concerned.

It is not always easy to find the answers. And it is even more challenging to draw conclusions from them. For example, market specifics can be difficult to understand and can evolve over time.

For TTOs, the complexity is reduced, as they typically promote only a limited number of technologies intensively due to constraints on resources for identifying partners and negotiating contracts. Consequently, TTOs need to rank their projects and invest in those at the top of their ranking in order to avoid the typical pitfall of spreading the available resources too thinly.

Evaluating IP

- Legal status
- Technology
- Market conditions

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Any evaluation of IP must focus on legal status, technology and market conditions.

Evaluation of legal status includes questions about patent status, ownership, enforcement means, and so on.

Evaluation of the technology should include questions on its uniqueness, stability and reproducibility, if it is superior to substitute technology, and how easy it is to identify infringing products.

The most crucial, but also most difficult, part of the evaluation is gaining a proper understanding of the market fit and dynamics. Questions to be answered include: "What are the commercial opportunities?" "What are the marketing options?" "Is freedom to operate easily achievable?" and "How big are the margins, turnovers and market growth rates?"

Slide 21

IP evaluation process

For university TTOs and SMEs wishing to evaluate the commercial feasibility of a new technology, the predefined time-scale associated with the filing and prosecution of a patent application effectively sets up a race against the clock for making decisions on investment in IP protection.

If the recommendation from the first evaluation is to file a priority patent application, it is essential to understand that several further evaluation activities will need to be conducted in parallel with the patent application process. These should serve to improve the quality of the information and the answers to the roughly 40 typical evaluation questions, which should assist in making the critical decision about whether the patent application should be pursued through the internationalisation and nationalisation stages of the prosecution.

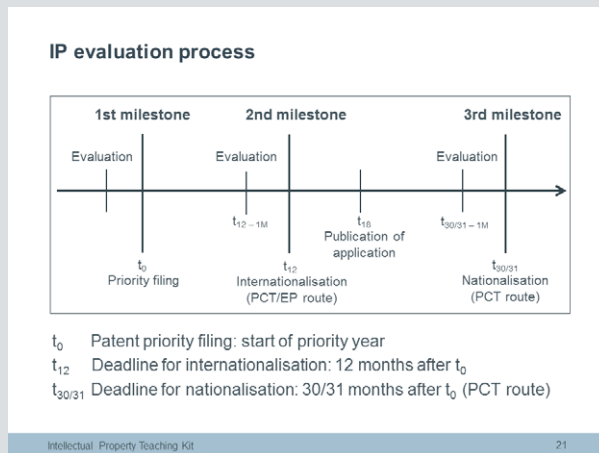
Sometimes documents regarding the ownership of an invention need to be complemented by additional agreements with former research partners which clarify and close off previously unsettled open issues.

The assessment of the patentability and scope of the patent claims could be improved if the search report, and in particular the search examiner's opinion regarding the cited documents, is obtained in sufficient time prior to making a milestone decision. In the case of a European patent application, the applicant can speed up proceedings at the search and examination stages with a written request for accelerated examination under the programme for accelerated prosecution of European patent applications (PACE).

The commercial relevance of the IP can be discussed with potential licensees and users of the products or services, which of course would generate information of significant value.

These are just a few examples of evaluation activities that could and should improve the analysis of and overall chances of success for a potentially commercialisable technology.

A good recommendation is to use the first evaluation as a starting point for planning the activity that needs to be completed by the next evaluation milestone, so that an informed decision can be made regarding subsequent investments in IPRs.



Based on the often preferred "cost-delaying strategy" for obtaining patent protection via the international route, we can draft a typical timescale for prosecution of a patent application during which the three main evaluation milestones occur. The first is the priority filing, the second, the start of the internationalisation, and the third, the start of the nationalisation.

Before an IP owner decides to go to the next milestone and consequently invest the money required for the patent attorney and patent office filing fees, he needs to evaluate the technology with respect to alternative options for the allocation of his resources to the most promising technologies.

At each stage of the evaluation, the same basic questions are asked, more or less, but the answers should provide increasingly more advanced information, which will enable the IP owner to make a better-informed investment decision.

Although the questions are basically always the same the answers are not, and the interpretation of the answers needs to relate to the specific commercial context. For example, product development based on new technologies for the fast-evolving ICT market typically needs to be at an advanced stage to gain approval for further investment. On the other hand, decisions on products being developed for the pharmaceutical market are influenced by a much different set of factors, including life cycles, margins and regulatory requirements. They would therefore normally have much longer lead-in times. A proposal for a pharmaceutical business spin-out may obtain financing for clinical trials several years in advance of the market launch for a developed drug.

Slide 22

How businesses exploit IP

There are many ways that companies can use their IP to create new commercial opportunities.

New product, process or service applications that are key to the business are protected as appropriate, with patents, copyright, trade marks, design rights, and so on, or are maintained confidentially as trade secrets and know-how. These are then available to defend its product development, manufacturing and sales activities.

From an external perspective, there are further possibilities to extract value from the IP and potentially generate revenue earning and investment opportunities. Generally speaking these are the same as for universities.

Co-operation

Co-operation opportunities for businesses take different forms than those for universities. They are often a good way to turn competitors into interdependent business partnerships. They may take the form of supply, distribution or manufacturing agreements, or focus on merger and acquisition deals. At the heart of the partnership is the exploitation of IP for mutual gain.

Licensing

A company's business strategy might focus on a particular product range for a specific market. However, its patent portfolio may contain patents that cover many different applications of the technology for sectors it is not strategically focused on, or where it does not have the expertise and resources to compete in those sectors. The company can open up new revenue-earning opportunities by offering licences for specific applications to other companies operating in those sectors.

Spin-outs

Spin-outs have been discussed in the previous slide dealing with universities. But they are not exclusive to universities. Companies successful in a particular business sector often see an opportunity to form a new company to exploit a

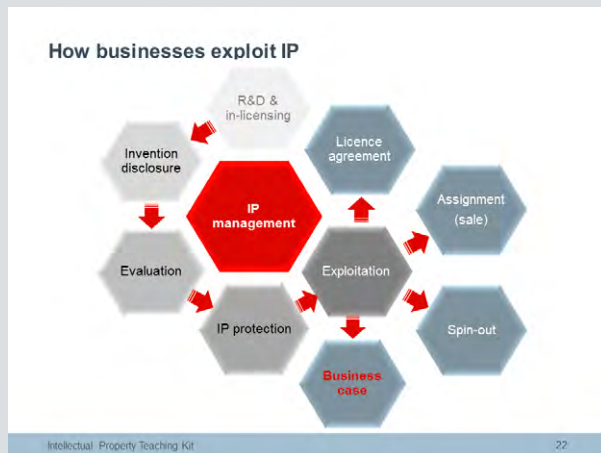
unique product or technology that is not aligned with its main business goals. To avoid distraction and disruption to its core business and the risks associated with entry into new markets, the company may decide to spin off that sector of the business and allow staff to form a new spin-out company to exploit these new opportunities. The IP associated with the product or technology may be a combination of patents, design rights, trade marks and know-how.

Sale

It may be that a company has redundant patents it acquired through mergers, or has changed direction in terms of its strategic focus and no longer requires the protection these patents afford. Selling them could be a lucrative deal. The company can therefore offer them for sale or auction and assign ownership to the purchaser.

Investment

The section on IP strategy mentioned how an IP portfolio might be presented as a set of valuable assets to attract investment.



This slide illustrates the ways in which companies use their IP to support their main business case. This includes internal strategies protecting product, process or service applications that are core to the business, and – as with universities – external strategies covering other possibilities for extracting value from the IP.

The main business case is usually based on selling products, processes and services. An additional component involves partnerships in the form of supply or manufacturing agreements or merger and acquisition deals.

As with universities, another possibility is licensing. Here a company may create new revenue-earning opportunities by offering licences for specific applications of its technology to companies it is not competing with.

Then we come to spin-outs. When companies are unable to exploit a unique product or technology because it is not aligned with their core business, they often spin off that sector of the business by forming a new spin-out company to exploit the new opportunities.

Next, a company may have redundant IP it has acquired through mergers, or because it has changed its business focus and no longer requires certain patents. It can offer this IP for sale or auction and assign ownership to the purchaser.

Last but not least, there is investment. In the section on IP strategy, I mentioned how a set of valuable IP assets can be used as collateral to raise investment from a range of sources such as private investors, business angels, venture capital companies and financial institutions.

Slide 23

Licensing IP

This slide introduces the legal principle behind licence transactions and explains the basic requirements of IP licence agreements.

Licensing IP

- Intellectual property rights
 - prevent others from using your inventions and creations
- Licences (contractual agreements)
 - allows others to use your inventions and creations
 - in accordance with specific terms and conditions
- Requirements for a legal contract
 - mutual exchange of a bargain
 - consideration (payment) exchanged for something of value (IP)



In the IP Basics module, we learnt that intellectual property rights are legal rights that can be used to prevent others from using your invention.

Patent owners can control the rights to use the IP by means of licence agreements containing an agreed set of terms and conditions.

Certain conditions must be met for a licence to constitute a legal agreement. There must be

- a mutual exchange of a bargain,
- a consideration – such as money, a licensee fee or royalties – exchanged for something of value, for example IP or other valuable assets, and
- a set of terms and conditions that make clear the intentions of the parties in their execution of the bargain.

Slide 24

Benefits of licensing

This slide compares the benefits associated with licensing from both the licensor's and licensee's perspective.

Benefits to the licensor

Revenues: For licensors, the opportunity to create a new source of revenue by leveraging IP has been covered in the earlier slides.

New markets & wider acceptance: By finding licensees in territories and markets that the licensor is not active in, a company can gain access to these markets and obtain wider acceptance and reputation for its products. This ensures that its technology and products penetrate the market faster and can even become the dominant design or standard in the industry.

Production and supply: Licensors can increase production capacity and sources of supply through manufacturing partnerships with their licensees. This ensures a steady supply of materials and products and reduces the risk of a single manufacturer not being able to respond to demand. Costs should be reduced through competition and allow a more competitive price point to gain wider market share.

Control: The reservation most licensors have in providing licensees with access to their technology is the risk of losing control over further development and improvements to the technology. Unless the licence agreement contains adequate provisions to control future developments to the technology, there is always a possibility that the licensor may get left behind in the next-generation versions of the technology. It is important, therefore, to ensure that the agreement contains terms for handling improvements, so that the licensor always has access to them.

Benefits to the licensee

Access to new technology: By in-licensing a technology, the licensee gains an opportunity for early access to a new technology, including knowledge and know-how, and possibly to new markets it is not in a position to compete in currently, all of which would take a lot longer if it were to develop the technology itself.

R&D costs: The licensee does not have to undertake the risk investments of finance, time and resources required to develop the technology in-house.

Competition: Access to a new technology can allow the licensee to stay competitive in the marketplace and match its competitors with new product features and product offerings.

Company assets: By in-licensing a technology and corresponding IPRs, the licensee effectively increases the asset value of the company and can use this new asset to its benefit in negotiations for credit, investment and acquisition deals.

Benefits of licensing

Licensor	Licensee
<ul style="list-style-type: none">▪ Create new source of revenues▪ Access new territories and markets▪ Influence market acceptance for technology and products▪ Create production and supply partnerships	<ul style="list-style-type: none">▪ Gain access to new technologies, turn-key products and processes and new markets▪ Reduce or avoid R&D costs and associated risks▪ Provide competitive advantage and IPR protection▪ Increase asset value of business

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The benefits of licensing for the licensor include the opportunity to create a new source of revenues by leveraging IP, and to gain access to new territories and markets. Also, by offering licences to leading firms in the sector, licensors can influence uptake and acceptance in the market as the preferred technology. They can use licensing to increase production capacity and create sources of supply through partnerships with their licensees. This reduces the risk of a single manufacturer not being able to respond to demand.

For the licensee, the benefits of licensing include gaining access to new technologies, turn-key products and processes and new markets, without undertaking the risk of investing time, money and resources in developing the technology in-house.

The licensee's business gains a competitive advantage in the marketplace by introducing new product offerings, which it can defend using the IPRs it now has at its disposal.

The licensed IPRs are effectively a new asset for the business, which will increase the value of the company on the balance sheet and which it can leverage in financial deals.

Slide 25

IP and spin-outs

It is now widely accepted throughout Europe that the creation of new technology start-ups and university spin-out companies is a major factor in reviving economic performance and generating new employment opportunities, so there is a great deal of encouragement and support at both national and EU level for programmes that offer financial assistance, plus a wide variety of training and coaching for entrepreneurship, business mentoring and the formation of start-ups.

Establishing a new start-up is a high-risk venture which requires energy, conviction and never-ending enthusiasm. The confidence to embark on this journey must, however, come from clear evidence that the business proposition is feasible. The decision will rely on a combination of the following four conditions to validate whether a start-up is ready to go:

- The technology has been demonstrated to work successfully for the intended commercial application.
- The commercial potential has been fully researched and market opportunity has been confirmed.
- The technology has been safeguarded with the appropriate IP forms, securing a strong and broadly protected IP position.
- The management team has a balance of complementary skills and expertise.

Securing finance will be the deciding factor whether a spin-out goes ahead or not. In most cases, the requirement will be for seed funding, but for some companies, particularly in the healthcare sector, larger amounts will be required to fund expensive clinical studies. Clearly, it will be important to present investors with convincing arguments for good commercial potential, but they will also need to be reassured that the assets that form the foundation of the company are validly protected, as it is the IP assets that ultimately secure the “monopoly” for the company’s future earnings and diminish the risk on their investment.

IP and spin-outs

- Decision to set up university spin-outs and new technology start-ups relies mainly on:
 - A demonstrated technology
 - Good commercial potential
 - Validly protected IP position
 - Strong management skills and expertise
- Investment
 - Start-ups generally lack positive cash flows.
 - Value lies in IP assets.
 - Investors base decision on strength of team and IP to protect future earnings.

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The decision to set up a spin-out relies on a combination of four main conditions. Firstly, that the technology has been demonstrated to work successfully for the intended commercial application. Secondly, that the commercial potential has been researched and market opportunity has been confirmed. Thirdly, that the technology has been secured with a strong and broadly protected IP position. And fourthly, that the management team has a good balance of complementary skills and expertise.

Generally speaking, new companies lack positive cash flows and require a seed investment. The IP and the team will be the only assets they have to leverage finance, so it is a very important element in influencing the decision to form a start-up. Investors need to be sure that the assets that underpin a company's technology and form its foundation are validly protected. It is these IP assets, in combination with the team,

that ultimately secure a kind of “monopoly” for the company's future earnings and diminish the risk to investors.

Slide 26

IP management case study

This is the title slide for this section of the presentation.

The aim of this case study is to illustrate what can go wrong when researchers engage in the exchange of information - in this instance the exchange of biological material and research results - without following the standard policies and procedures widely adopted by universities today.

It is an account of a real-life event which resulted in an unfortunate set of consequences for a research institute, two private companies and the scientists involved.

The case study will highlight how poor management of IP at the planning stage of a research project and the initial reporting of an invention led to a situation where incorrect inventorship arose, with significant financial consequences for the owner and licensee of the invention many years later.

Lessons drawn from the mistakes that occurred will emphasise the importance of following standard policies and procedures that are designed to ensure that the fundamental rights at the point of creating intellectual property, inventorship and ownership of inventions are appropriately evaluated and assigned.

IP MANAGEMENT CASE STUDY

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This is an interesting case study about a real-life event. I think it highlights some very practical elements that illustrate how a casual approach to IP management at an early stage of a research project can lead to serious consequences later on in the commercialisation of the IP.

This case study is the story of a research group that was working on developing a treatment for cancer.

During the project one of the researchers had a conversation with a former colleague regarding a biological material she required for her experiments. He agreed to provide her with material he had developed, which he thought might work in the project.

When the project finished there was an interesting finding that was thought might have potential benefits in the treatment of cancer. This finding became the subject of a

patent application. Lack of management of IP led to a situation where incorrect inventorship arose, a fact which had significant financial consequences for the owner and licensee of the invention many years later.

The objective of this case study is to illustrate what can go wrong when researchers engage in the exchange of information without following the policies and procedures widely adopted by universities today. As I present the different events in this story, I would like you to think about how things might have been done differently and what procedures you think could have been put in place to avoid the mistakes that occurred. We can discuss these at the end of the slides and see what lessons we can learn from this unfortunate set of circumstances.

Slide 27

Background

The antibodies in this case study can be tailor-made to have an affinity for a specific site on certain cancer cells. By developing these antibodies, well-known chemotherapeutic drugs can be chemically attached to them, allowing the drug therapy to be carried straight to the site of the tumour and not randomly throughout the body.

Background

- Scientists at the Weizmann Institute conduct research on using antibodies as carriers to target treatment for specific cancers.
- A former colleague provides materials for use in experiments.
- Promising results are obtained.
- A patent application is filed.
- The patent is licensed to a biopharma company.
- Ownership of the patent is disputed.
- Litigation proves costly.

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The story begins in 1987, at the Weizmann Institute of Science in Israel, where a group, under the direction of Professor Sela, was conducting research on treatments for cancer using the method of attaching chemotherapeutic drugs to monoclonal antibodies so that treatment could be targeted to the specific site of the cancer.

A former colleague, Professor Schlessinger, paid a visit to the Institute and, after a chance meeting with one of the researchers, agreed to send her some antibodies he had made which might be useful for her project.

The results were very promising, and Sela's group prepared a paper for publication.

Meanwhile, Schlessinger's group drew up a patent application.

The patent was eventually licensed exclusively to a pharmaceutical company for the commercialisation of a cancer treatment.

When Professor Sela discovered that his group's research had resulted in a patent, a dispute ensued. The dispute was not resolved and ended in litigation in the courts of New York, which proved very costly for the companies that owned and licensed the patent.

Slide 28

The research programme

The objective of Sela's research was to develop treatments for cancer that were based on a method of targeting the drug treatment to the specific location of the tumour in the body, allowing a more effective chemotherapy to be delivered at the specific site and avoiding the cytotoxic affects these drugs have on normal healthy cells.

Researchers on the project were having difficulty in sourcing monoclonal antibodies that had the required specificity for the type of cells they were working with. Through a chance meeting with Professor Schlessinger – a former colleague of Professor Sela then working on sabbatical leave at US biotech company Rorer Biotechnology Inc. – the researchers received a gift of some antibodies from him to test in their experiments.

One of the antibodies was selected and subsequently played an important role in their project.

The research programme

- Objective: to target cancer cells with a chemotherapeutic drug.
- Sela's research group at the Weizmann Institute received two monoclonal antibodies (mAb) from former colleague Professor Schlessinger.
- mAb binds to specific site on cancer cells (selective targeting).
- One mAb selected for experiments.
- Drug chemically linked to mAb (conjugated).
- Effects targeted delivery of chemotherapeutic drug.

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As I just mentioned, the objective of Professor Sela's research was to develop treatments based on a method for targeting the drug treatment to the specific site of the cancer.

Professor Schlessinger – a former employee of Sela working on sabbatical leave at a US biotech company – had made monoclonal antibodies that were specific to certain types of cancer cell and agreed to send two such antibodies to the group to test in their experiments.

The group did some preliminary testing and selected one of the antibodies to use in the research project.

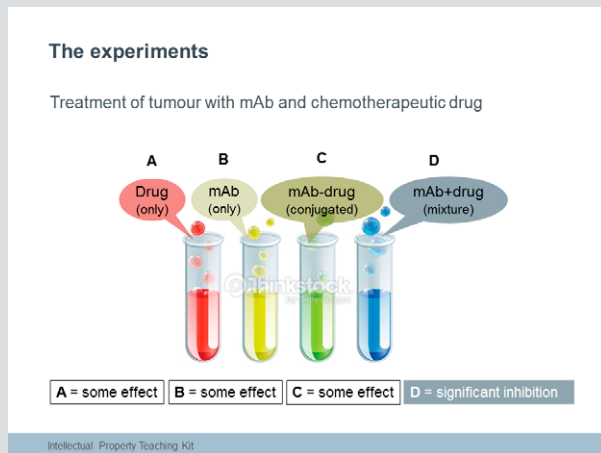
In chemically linking some known chemotherapeutic drugs to the antibody, the theory was that the antibody would carry the drug straight to the cancer cells, where it would

work more efficiently than traditional drug administration therapies.

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The experiments

Initially three experiments were designed and the expectation was that, if the drug was being carried by the antibody straight to the site of the tumour, then experiment C should be the most effective treatment and should demonstrate greater inhibition of tumour growth than either of the other two treatments (A and B). After analysis and discussion of the results, a further experiment, D, was carried out.



In a series of experiments, a tumour was implanted in mice to see which of the treatments would be most effective in inhibiting growth of the tumour.

In experiment A, the selected chemotherapeutic drug was injected on its own.

In experiment B, the antibody was injected on its own.

In experiment C, a conjugate of the antibody and drug – the substances are chemically linked – was injected.

After discussion of the results, a fourth experiment was proposed.

In experiment D, the antibody and the drug were combined in a mixture, in which they were not chemically linked, and injected.

In each of the experiments A, B and C there was evidence of some growth inhibition in the tumour. But when experiment D was completed, it was evident that this provided the most efficient growth inhibition. A synergistic effect was observed, where the inhibition on tumour growth was far greater than the sum of the two separate substances acting alone.

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The results

The results of the experiments were surprising. Experiments A, B and C all showed an inhibitory effect on cell growth in the tumour, but they did not eliminate the tumour entirely.

Experiment D showed greater efficiency in inhibiting cell growth in the cancer cells. The mixture of the two components was exhibiting a synergistic effect, i.e. an effect greater than the sum of the parts.

It was also discovered that the drug was still effective in the mixture when administered at much lower levels than those required for inhibitory effects when administered on its own. So, not only did the mixture experiment demonstrate a superior inhibitory effect on tumour growth, but it could also achieve this at lower concentrations of the drug. This could have significant safety and economic benefits in human therapies where high levels of chemotherapeutic drugs are cytotoxic to healthy cells and where the cost of these drugs is directly related to their concentration.

The results

- Expectation that **experiment C** would show best results
 - mAb should carry drug directly to tumour and destroy cancer cells.
- **Experiment D** shows a surprising effect
 - Free mixture of chemotherapeutic drug and mAb creates synergistic effect on inhibiting growth of cancer cells.
 - Unpredicted result demonstrates "inventive step".

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The researchers were, of course, expecting experiment C, the one with the antibody-drug conjugate, to work the best, because they expected the drug to be delivered directly to the site of the tumour.

Surprisingly, however, it was experiment D that produced the best effect. The mixture exhibited a synergistic effect. It demonstrated a superior inhibitory effect on tumour growth, at lower concentrations of the drug.

This had not been predicted by the scientists, and as such it was surprising and inventive.

Slide 31

The publication

The publication

- Sela did not consider filing a patent application
 - mAb owned by Schlessinger's employer, Rorer Biotechnology.
 - Might give rise to complex negotiations.
 - Happy to disseminate results in *Journal of the National Cancer Institute*.
- Sela's group prepares publication
 - Draft of paper shown to Schlessinger on next visit.
 - Schlessinger also named as author for contribution of mAb.
 - Paper published in December 1988.

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However, Professor Sela did not consider patenting this invention, as the antibody they had used was the property of Rorer Biotechnology Inc., the company where Professor Schlessinger worked.

Sela felt it would involve a tedious internal approval process and complex negotiations with Rorer.

He was happy, therefore, to simply disseminate the promising findings in a scientific journal.

The group prepared a publication and, on his next visit, provided Schlessinger with a draft copy, in which he was named for his contribution of the antibodies.

The paper was then published in the Journal of the National Cancer Institute in December 1988.

Slide 32

The patent application

While Professor Sela's group was preparing to publish the results of the research, the team at Rorer had decided to initiate clinical studies on the antibodies and file a patent application to protect them for use in cancer treatments. This slide explains the sequence of events that unfolded.

The patent application

Schlessinger discusses results with colleagues at Rorer:

- Clinical studies initiated.
- Patent application prepared.
- Claimed "antibodies" + "antibody/drug mixtures" in cancer treatment.
- Inventors named are all Rorer employees.
- US patent application filed September 1988 (unknown to Weizmann).

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On his return to the US, Professor Schlessinger discussed the draft paper with his colleagues and it was decided that the company should submit a US patent application.

They began clinical trials and prepared a submission for FDA approval.

A patent application was drafted which included claims for the protection of the Rorer antibodies in the treatment of cancer.

But it also had claims for a mixture of antibodies with chemotherapeutic drugs – precisely the inventive step that Professor Sela's group had demonstrated in the experiment showing the synergistic effect of the mixture.

Only Rorer inventors were named in the application.

Unknown to the Weizmann Institute, the application was filed in September 1988, shortly before the publication of the Weizmann Institute paper in December 1988.

Prosecution of the patent was a lengthy process, but it was finally granted in the US in 2001.

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The licence

The licence

- 1994: Rorer grants exclusive licence to ImClone.
- ImClone invests USD 190m in developing cancer therapy.
- 1999: Aventis acquires Rorer and patent after series of mergers.
- "Erbix" receives FDA approval:
 - 2004: colorectal cancer
 - 2006: head and neck cancer
- 2007: sales of "Erbix" in the order of USD 400m per year.

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In the meantime, in 1994 an exclusive licence was granted to ImClone, who invested 190 million dollars in developing a cancer therapy.

Through a series of acquisitions and mergers, the patent changed ownership over a number of years, before finally becoming the property of Aventis in 1999. ImClone continued to be the exclusive licensee.

The drug that was eventually developed was called "Erbix". It was approved by the FDA for the treatment of colorectal cancer in 2004, followed by head and neck cancer in 2006.

By 2007, sales of the drug had reached 400 million dollars a year.

Slide 34

The patent dispute

When the US patent was granted and published in 2001, it was the first time it had become public knowledge. Professor Sela was surprised to learn that a patent application had been filed which he felt was based largely on the work carried out by his group. Yeda, the technology transfer company that represents the Weizmann Institute, intervened to determine the ownership of the patent but, failing to come to a resolution with Aventis and ImClone, it commenced proceedings in the US courts against both parties.

The patent dispute

- 2001: Patent granted and published (US6217866):
 - US patent limited to claims for mAb/drug mixture.
 - Other territories grant claims to mAb only and to mixture.
- 2002: Sela becomes aware of patent and raises concerns.
- Yeda (technology transfer company for Weizmann Institute) enters discussions with Aventis and ImClone → no resolution.
- 2003: Yeda starts court proceedings against Aventis and ImClone.

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The US patent was granted in 2001 under the number US6217866. The claims granted were to the mixture of antibody and drug only.

However, in other countries claims directed to treatments using the Rorer antibodies only and to use of the mixture were allowed.

Professor Sela was surprised and perturbed to learn that a patent application had been filed which was based mainly on the work carried out by his group.

Yeda, the technology transfer company that represents the Weizmann Institute, was informed. It initiated discussions with Aventis and ImClone to have the Weizmann scientists named as inventors and for ownership of the patent to be changed to joint ownership.

However, a resolution was not forthcoming and in 2003 Yeda commenced proceedings against Aventis and ImClone.

Slide 35

Litigation

In 2006, a bench trial was held in the District Court of New York. This slide outlines the case presented by the two sides.

Litigation

- Yeda's case
 - Experiments and inventive concept originated solely from Sela's group.
 - Data and figures for patent specification drawn from draft publication.
- Defendants' case
 - Provided mAb for the experiments.
 - Schlessinger advised Weizmann scientists on the project.
 - Had already contemplated mixture of mAb and drug.

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Yeda claimed that the invention relating to the mixture was based on experiments designed and performed exclusively by the Weizmann scientists.

It also pointed out that the patent specification had been drafted using figures and text copied from the paper Professor Sela's group had prepared for publication of the results.

Their initial motivation was to have the patent corrected for joint ownership, as there were some claims in the patent directed to use of the Rorer monoclonal antibodies for the treatment of cancer only. However, during prosecution of the patent, these claims were not allowed by the US Patent and Trademark Office. Yeda then changed its case to full ownership of the patent, as the Rorer scientists had not contributed to the mixture experiments.

The Aventis/ImClone defence was that Professor Schlessinger and the Rorer scientists were the true inventors, as they had provided the antibodies for the research project.

Schlessinger also claimed that he had advised the Weizmann scientists on conducting the research project and had already contemplated the mixture experiment himself.

Slide 36

The court decision

Judge Buchwald found in favour of the Weizmann scientists and directed that ownership of the patent be corrected at the USPTO.

The most important piece of evidence that led to the decision in this case was the clearly documented information showing all the project planning and experimentation leading up to and relating to the mixture experiment. This is where the concept of the invention originated, and the laboratory notebooks at the Weizmann Institute had been properly maintained with all the relevant entries relating to this work.

Schlessinger and his colleagues, on the other hand, had no records to show that they had either performed or in any way influenced the mixture experiment. The evidence they presented in relation to the mixture experiment was mainly oral and based on the memory of conversations that had taken place nearly twenty years earlier.

This slide explains the court's decision and the terms for the out-of-court settlement reached between the parties.

The court decision

- Weizmann scientists are sole inventors of US patent.
- Inventorship of patent corrected at USPTO.
- Yeda becomes owner of patent.
- Out-of-court settlement reached 2007:
 - Yeda owns US patent.
 - Yeda and Aventis jointly own patents in other territories.
 - Aventis and ImClone pay USD 60m each to Yeda.
 - ImClone pays Yeda royalty on sales in US.
 - ImClone pays Yeda and Aventis royalty on sales outside US.

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On reviewing the laboratory notebooks from both sides and hearing the testimonies of the researchers involved, the judge found in favour of the Weizmann scientists as being the sole inventors.

She requested that the patent be corrected for inventorship at the USPTO, to show only the three Weizmann scientists as inventors.

Ownership of the patent was then assigned to Yeda, acting on behalf of the Weizmann Institute and the scientists.

In 2007 the parties reached an out-of-court settlement. Yeda was the owner of the US patent. Patents granted outside the US contained claims to the use of both the mixture and the antibodies on their own in treating cancer. For this reason, it was agreed that these patents would be jointly owned.

It was also agreed that Aventis and ImClone would each pay a lump sum of 60 million dollars to Yeda.

Additionally, in return for a worldwide exclusive licence, ImClone agreed to pay Yeda a royalty on sales of Erbitux in the US.

For sales of the drug outside the US, ImClone would pay a royalty to both Aventis and Yeda.

Slide 37

Note on inventorship

We can learn a valuable lesson from the judge's decision on how inventorship is determined.

The defendants' argument for entitlement to inventorship was that they had provided the antibodies for the experiments and that, if these had not been provided, there would have been no invention. The judge's response to this is that the outcome of what happened merely because of a person's contribution does not necessarily imply entitlement to inventorship. The only argument that needs to be considered in determining inventorship is who contributed to the "concept" of the invention. The "concept", in this regard, is the mental process of repeating the invention. In other words, the inventor devises the steps that give rise to the inventive step and has a mental concept of what physical acts need to be done to make it work. In this invention, the act of combining the monoclonal antibody with the chemotherapeutic drug in a free mixture was the inventive concept.

There may be other parties who carry out some of the work, but if they are only operating under the instruction of the person who has already conceived of the "concept", then they are not the inventors. Anyone who is entitled to be named as an inventor must have actually contributed to the "concept" of the invention.

Many researchers might automatically include colleagues in the list of inventors in recognition of their contribution to work on an invention that has been completed jointly. This may be appropriate protocol in deciding authorship of a paper. However, on the question of inventorship, it is very important that they clearly understand the requirement for a contribution to the concept of the invention. If incorrectly assigned it may have serious legal implications.

Note on inventorship

Judge Buchwald: *"Conception is the touchstone of inventorship, the completion of the mental part of invention."*

- The inventors are those who conceived of the idea of using the mAb in an unconjugated mixture in order to treat human tumour cells.
- The provision of mAb alone does not give entitlement to inventorship.
- There was no evidence of collaboration or contribution to conception or reduction to practice of the invention by Schlessinger's group.

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We can learn a valuable lesson from the judge's decision on how inventorship is determined. She stated that "conception is the touchstone of inventorship, the completion of the mental part of the invention." What did she mean by this?

The argument that needs to be considered in determining inventorship is who contributed to the "concept" of the invention. The "concept" in this regard is the mental process of repeating the invention. In other words, the inventor discovers the important steps that give rise to the inventive step and has a mental concept of what physical acts need to be done to make it work. In this invention, the act of combining the monoclonal antibody with the chemotherapeutic drug in a free mixture was the inventive concept.

The defendants' argument for entitlement to inventorship was that they had provided the antibodies for the experiments and that, if these

had not been provided, there would have been no invention. The judge's response was that the outcome of what happened merely because of a person's contribution does not necessarily imply entitlement to inventorship.

Professor Schlessinger and his colleagues had no records to show that they had either performed or in any way influenced the mixture experiment, nor that there was any act of collaboration with respect to the concept.

Slide 38

Discussion

Refer to the background information to "Lessons learnt" (next slide) to guide the discussion on this point.

Ask the students to consider what procedural steps might have been introduced in the two organisations involved that could have prevented the situation of incorrect inventorship arising. Central to this will be an understanding of what actually constitutes inventorship, as explained in the previous slide.

Discussion

What procedural steps might have been introduced in the two organisations involved that could have prevented the situation of incorrect inventorship arising?

Slide 39

Lessons learnt

The issues that need to be considered are as follows:

Non-disclosure agreement

Discussions between Professor Sela's group and Professor Schlessinger regarding the research project at the Weizmann Institute were conducted in a rather informal manner. Schlessinger was an employee of the institute, but at that time he was on sabbatical leave working for a US company. This is not an untypical situation in academic research organisations. But in such situations familiarity between colleagues can often cause a casual approach to be taken with respect to set procedures. How should the parties have conducted their discussions?

It is difficult to be prescriptive, but where the discussion means there will be an exchange of project details, such that experimental models and conceptual aspects of potential inventions are disclosed, the participants must exercise caution and be aware of the recommended procedures, particularly if such discussions take place with an employee of a company whose objectives are clearly commercial.

In the Schlessinger/Weizmann case, the parties should have executed an NDA before divulging details of the project. Not only would it have been important to Sela's group, but Schlessinger, on behalf of Rorer, had also disclosed company information regarding his antibodies, which he should only have done under confidential terms. The disclosure of the draft publication, which contained all the relevant details of the inventive concept, should also have been provided under confidential terms.

If in doubt, your university's technology transfer office can provide guidance on how to conduct discussions with colleagues or third parties outside the university.

Material transfer agreement

The exchange of antibodies was critical to the final results in the Weizmann project and led to the creation of a very commercial invention.

Professor Schlessinger should have ensured that the antibodies were transferred to the Weizmann Institute under the terms of a formal material transfer agreement

(MTA). MTAs are similar to NDAs in that they stipulate terms for maintaining the material confidential. However, they also provide more detailed conditions with respect to ownership and use of the material, the reporting of results, the submission of publications containing data generated by use of the material and what happens if inventions result from use of the material. Schlessinger's employer did have a company MTA and it was policy to use it for such exchanges of materials, but on this occasion none was completed, perhaps because of the familiarity and informal nature of the discussions that took place. The Weizmann Institute no doubt also operates a policy of using MTAs, and had the scientists informed technology transfer office staff that they were to receive monoclonal antibodies for their research project, the TTO would surely have asked to see the terms for this exchange and advised on any implications that might arise from using the antibodies.

Again, the completion of an MTA would have had the benefit of increasing awareness between the parties regarding the possible creation of an invention using the antibodies. It would have raised questions about how such inventions should be reported, who the inventors might be and the eventual ownership of any patent applications that might be filed.

Invention disclosure forms

Most organisations, in both business and academia, use invention disclosure forms (IDFs) to capture inventions arising from their research programmes. These forms are fairly standard in their content and typically contain questions designed to extract specific information regarding the inventive step, the personnel who completed the work and any third party input to the work, in the form of either actual work on the project, or the provision of key information and material. An IDF is therefore an important tool in the process of capturing and evaluating inventions, and it is the analysis of this information that usually determines who the inventors are.

If Professor Schlessinger's company, Rorer, had requested the completion of an IDF prior to filing the patent application, the information provided in the form would probably have initiated probing questions about who the inventors on the patent should be.

E

Lessons learnt

- Exercise caution in disclosing research results → use an **NDA**.
- Clarify terms for exchange of materials → use an **MTA**.
- Complete an invention disclosure form (**IDF**) to help inventors focus.
- Keep **notebooks** to provide convincing documentary evidence.

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The first issue to consider is the failure to sign a non-disclosure agreement or NDA. The disclosure of the draft publication, which contained all the relevant details of the inventive concept, should have been provided under confidential terms.

The second issue to consider is the failure to sign a material transfer agreement or MTA. The exchange of antibodies was critical to the final results in the Weizmann project and gave rise to the creation of a very commercial invention. Schlessinger should have ensured that the antibodies were transferred to the Weizmann Institute under the terms of a formal material transfer agreement (MTA).

The third issue is the failure to use an invention disclosure form or IDF. Most organisations, in both business and academia, use them to capture and evaluate inventions arising from their research programmes. The analysis of this information usually determines who the

inventors are. If Rorer had asked Schlessinger to complete an IDF, the information provided would probably have initiated probing questions about who the inventors on the patent should be.

Finally, the most important evidence in this case was the clearly documented information showing all the project planning and experimentation leading up to and relating to the mixture experiment. This is where the concept of the invention originated. The laboratory notebooks at the Weizmann Institute had been properly maintained with all the relevant entries relating to the work. Schlessinger and his colleagues, on the other hand, had no records to show either that they had formally collaborated with the Weizmann Institute, or that they had performed or in any way influenced the mixture experiment.

Laboratory notebooks

In reaching her decision on who the true inventors were, the judge relied heavily on documented evidence showing the research experiments that led to the invention. The Weizmann Institute was clearly operating a good-practice notebook policy, as its scientists were able to produce notebooks complete with experimental data showing the development of the invention each step of the way. The Rorer scientists, on the other hand, had poorly documented evidence, and none that was relevant to using the antibodies in the mixture experiment to inhibit tumour growth.

This is an important lesson to take from this case study, as notebooks are probably the most meaningful tool in resolving disputes surrounding entitlement to inventorship and, subsequently, ownership of IP. Anyone involved in creative work of any nature should implement a notebook procedure to document all stages of the work leading to the final innovation, whether it is an invention (patent), a design or copyright material.

Further reading

For more details see pages 129 – 135, *Yeda v ImClone and Aventis*, in:

Intellectual Property: From Creation to Commercialisation, John P. Mc Manus, ISBN 9781781190241



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Graham Barker
Silvia Baumgart
Robert Harrison
Anu Idicula
Ingrida Karina-Berzina
John Mc Manus
Sérgio Maravilhas Lopes
Anna Yotova

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