Go8
Future Research Leaders Program

Module 4: Intellectual Property & Commercialisation

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Module 4:

IP & Commercialisation

Go8 Future Research Leaders

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- Intellectual Property
- Recognising the potential of your research and understanding the market
- Workgroup Session 1

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- General Discussion

Commercialisation: an overview

Commercialisation – what is it?

Macquarie Dictionary

- **commercialise** *to make commercial in character, methods or spirit; make a matter of profit*
- **commercial** *capable of being sold in great numbers; setting possible financial return above artistic considerations*

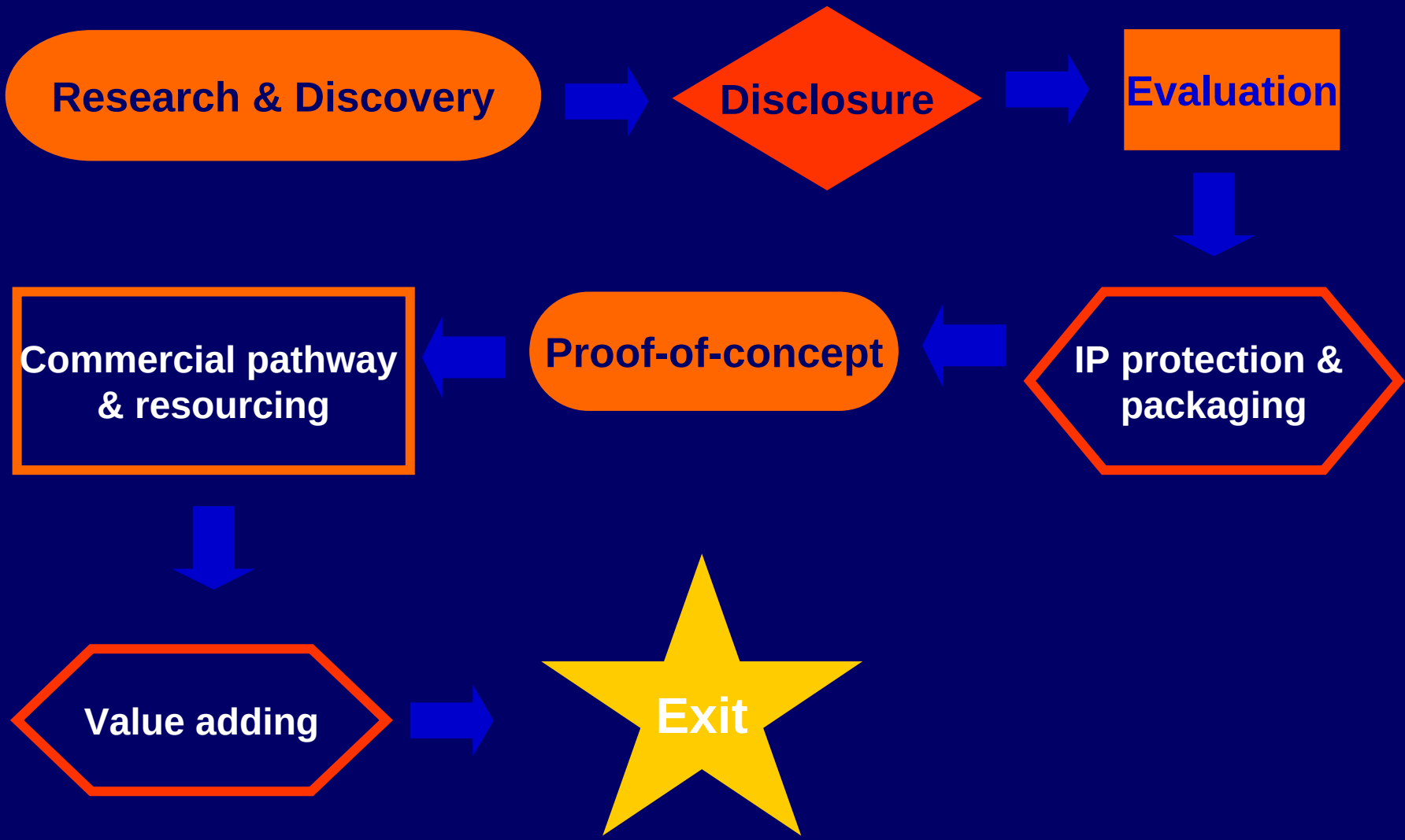
- In a University Context:

'The process of managing the transfer of research outcomes to broad market application'

Why commercialise?

- Satisfaction of bringing benefits to society
- Personal economic gain
- National economic, social and political imperatives
- ‘No strings’ funding for further research
- Ability to break free of the competitive grants cycle
- Relative autonomy
- Career advancement, expanded career options and enhanced ‘employability’
- Professional development and peer recognition

The commercialisation process:



Key points in the commercialisation process:

- **Research & Discovery**
  Structure the research program to maximise commercial outcomes
- **Disclosure to the Office of Commercialisation**
  As early as possible
- **Evaluation**
  Assessment of commercial potential
- **IP protection & packaging**
  And continued research to support commercial efforts

- **Proof-of-concept**
  Critical research to prove the innovation ‘works’; essential to secure investment

- **Pathways & resourcing**
  Start-up or licensing opportunity?

- **Value adding**
  Developing the “product” for the market

- **Exit**
  The point at which the stakeholders sell or exchange a significant amount of company ownership, generally, to realise an economic gain

Intellectual Property

Intellectual property is …

The product of your mind or intellect

It is intangible in nature

It exists in several different forms

It can be bought and sold, rented (licensed) and destroyed

Types of Intellectual Property

- Patents
- Trade marks
- Plant Breeders Rights
- Registered Designs
- Copyright
- Circuit Layouts
- Confidential Information

Patents – The Basics

"An agreement between the owner of an invention and the government of the country, in which the owner agrees to publish the invention, and in return the government agrees to give the owner exclusivity on the use of the invention for a limited time."

- A patent is often thought of as a monopoly right to exploit an invention

What Can You Patent?

- New product, new result, new combination
- Manner of new manufacture
- Mechanical device
- Chemical process
- Practical application of a computer process
- Business schemes

"Everything under the sun made by man is patentable"
US supreme court, 1980

Patents

- There is no such thing as a worldwide patent
- Each country grants patents separately
- The national systems are harmonising through
  - the patent cooperation treaty (PCT),
  - the World Intellectual Property Organisation (WIPO),
  - trade related aspects of intellectual property rights agreement (TRIPS),
  - Free Trade Agreements (FTA)
  - and bilateral cooperation

- Important differences remain between the systems in each country
- A standard patent lasts for 20 years, after which no patent protection exists (although other forms may apply)

Criteria for a Patent

For a patent to be granted for an invention it must meet **three** criteria:

1. **Novelty:**
   - Has it been known, used or published before?
   - **Remember -** Academic publication or conference presentation will invalidate a patent.
   - (Talk to the Office of Commercialisation first)

2. **Inventiveness (non-obviousness):**
   - Does it have an inventive step?
   - Could anyone, skilled in the art, have done it?
   - Complexity is not sufficient!

3. **Commercial utility:**
   - Is it useful for anything?

Typical Patenting Process

What is a trade mark?

- Sign (word, logo, aspect of packaging, shape, sound, smell)

  Anything that a product manufacturer believes distinguishes their product from another

- Needs to be different (not the same or deceptive)

- Non descriptive

- Initial registration of a trade mark lasts for 10 years, renewable for ever in blocks of ten years.

Copyright

- Copyright protects the original expression of ideas, not the ideas themselves.
- It is free and automatically safeguards original works of art, literature, music, films, broadcasts and computer programs from copying or use.
- Material is protected from the time it is created.
- Material may also enjoy reciprocal protection under the laws of other countries who are signatories to the *universal copyright convention.*
- Lasts for life plus

Registered Design

- A design relates to the features of shape, configuration, pattern or ornamentation which, when applied to a product, gives the product a unique appearance.

- Design registration is used to protect the visual appearance of an article, not how it works.

- The design must be new and distinctive.

Registered Design (cont..)

- A registered design gives you the exclusive and legally enforceable right to exploit your design.
- Protection is for 5 years, renewable for an extra 5 years.

Confidential Information or ‘trade secrets’

A ‘trade secret’ exists if:

- There is a relationship of confidence
- The trade secret is not in the public domain
- There exists a confidential regime to protect trade secrets

  e.g. Material Transfer Agreements, Confidentiality Agreements, Physical Security

If IP is not protected, its commercial value is lowered

- Therefore it is less likely that the product of your research will ever become a product in the marketplace

Awareness of IP and its value is an increasingly important part of life as a researcher

- Disclosure of information (*e.g.* publication) can destroy patentability
- Commercialisation can be a source of funding, recognition and reward for innovators/inventors

However, …

Patenting and commercialisation DO NOT prevent publication.

Once patented, a concept can then enter the academic literature.

IF you think your research has commercial potential, talk to the Office of Commercialisation

Importance of maintenance of lab books

- First to file - Australia
- First to invent – United States
- Lab books important in ‘first to invent’ system
- Lab books can be used as evidence to obtain patent protection in ‘first to invent’ countries

Lab book best practice

- In a competition between two lab books, the one that complies with best practice is likely to be successful
- It is all about strengthening credibility and trustworthiness of what is recorded
- Looking for a methodical, reliable and diligent inventor
- If best practice is not followed the patent may be put at risk, even if truly invented first

Confidentiality Agreement

A disclosure puts the innovation into the public domain, a disclosure can be:

- publishing a paper
- presenting at a conference (orally or via poster/abstract)
- publishing the information on your or your institute's website
- publishing the information in an Annual Report
- even discussions with just one person

Disclosure affects the ability to patent

Need for obligations of confidentiality

- A Confidentiality Agreement or Non-Disclosure Agreement can allow limited disclosure of confidential information without prejudicing patentability. Again – talk to the Office of Commercialisation.

Material Transfer Agreements

Fundamentally a Confidentiality Agreement

- disclosure of information *and*
- provision of biological material

Owner provides material and information

Recipient receives material and information

Similar obligations to a Confidentially agreement

- secrecy
- non use

Common terms of a Material Transfer Agreement

Possession of Material

Security of Material

Use of material

- evaluation
- human use/animal use
- ethical codes

No warranties

- about material
- safety / toxicity etc

Issues in a Material Transfer Agreement

Ownership of progeny and derivative material

- virus from virus
- clone from cell line
- protein from DNA

Ownership vests in

- owner of material; or
- recipient who develops

Disclosure of Evaluation Results

Term / Duration

Return of Material, Progeny and Derivatives

Recognising the potential of your research

Does your research benefit society?

Would the public want to purchase your technology, product or service?

How do you identify a commercial opportunity?

What is the Product?

Tangible item

- Compound (e.g. antibody)
- Device

Process or method

- Manufacturing or production method

Service

- Provider of antibodies, isolated cells, etc

Is the technology of value?

Assessing the Opportunity

Key factors to consider:

- ✓ Intellectual property position
- ✓ Market
- ✓ Competitors
- ✓ Competitive advantage
- ✓ Customers
- ✓ Other factors (regulatory, political)

Structuring your research program

1. Start with the end in mind - what do you want?

2. Define the unique selling point of your research

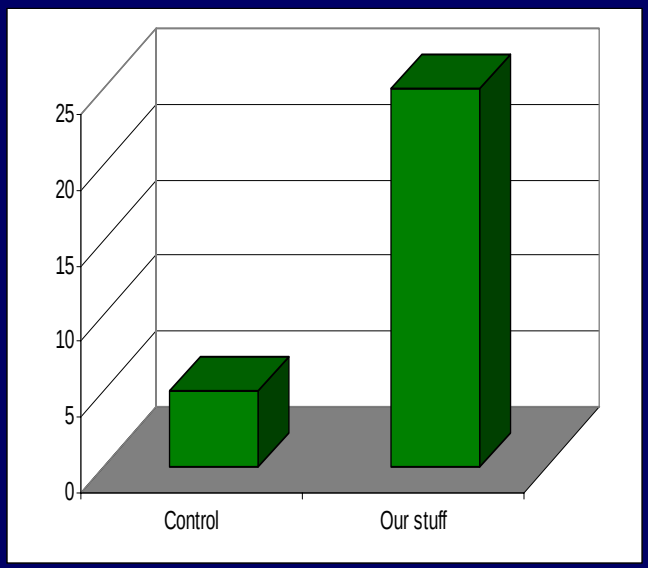
3. Recognise that the research or expertise may need to be developed

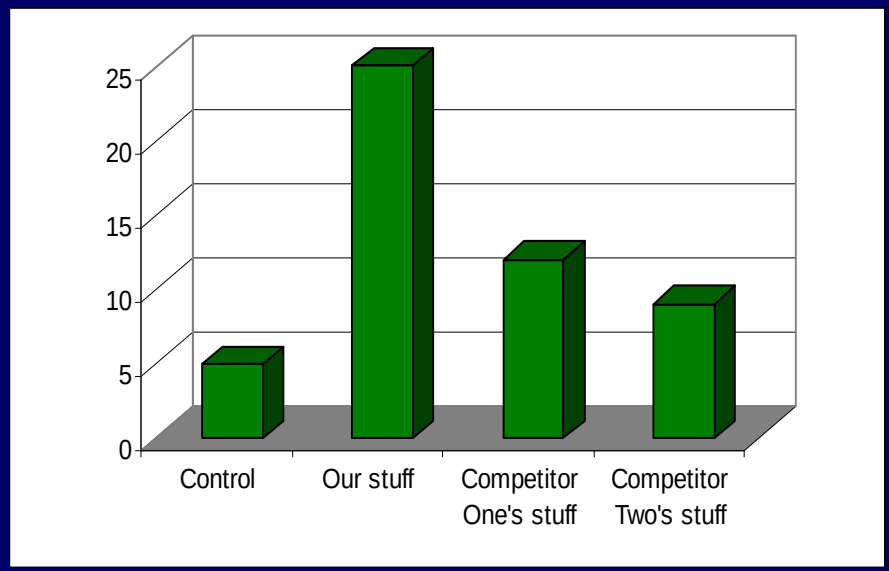
Key elements to develop research

1. Proof of concept / demonstrate the research work has value and understand why
2. Compare with competition
3. Develop the product
4. Assess and protect relevant intellectual property involved

The killer slide

An experiment or research result that clearly proves the value of the research compared to existing products or methods.





Can create the “million dollar slide”

An “External World” Product
Is it worth all the trouble?

Show how the research can be converted into something “sellable”

- Cost of production/provision of services
- Scale up/production issues – raw materials
- Regulatory issues
- Time to market
- Cost of sales, marketing & distribution
- Risk: technical, market, IP

The larger the potential return, the more risk that will be accepted

To consider:

- Markets change quickly – it can be a race to develop your product/technology/service/business first
- Need to be committed, not just involved
- Need to be passionate but also rational: not all research with commercial potential will be a commercial success

Aspects of Commercial Research - general good practice

- Commercial projects are often milestone driven
- Reporting may be quarterly, or more frequent
- Lab notebooks under commercial practice
- Publication conditions
- Confidentiality provisions
- Patent filing and support
- IP ownership
- Involvement of students – IP ownership, publications, thesis

Workgroup Sessions 1 & 2

Entering the market

Licences & Start-ups

The licensing pathway

What is a licence?

- Permission or grant to exploit intellectual property
- Like a lease for a rental property
  - Licensor = landlord
  - Licensee = tenant
- Does NOT transfer ownership of the IP
- Licence agreement = Contract
  - Creates rights, duties and obligations for parties
  - Legally enforceable
- Terms of a licence are flexible between parties
  - Common ground; “win-win”

Why license?

Advantages:

- Relatively low cost to set up
- Provides a return with minimal outlay
- Minimises the licensor's involvement in exploitation
- May overcome foreign barriers

Disadvantages:

- Returns commonly less than expected
- Administration costs higher than expected
- Licensee may not perform (performance requirements)
- Minimal control over management of licensee
- Loss of control of trade secrets
- Create a future competitor

Why companies license research?

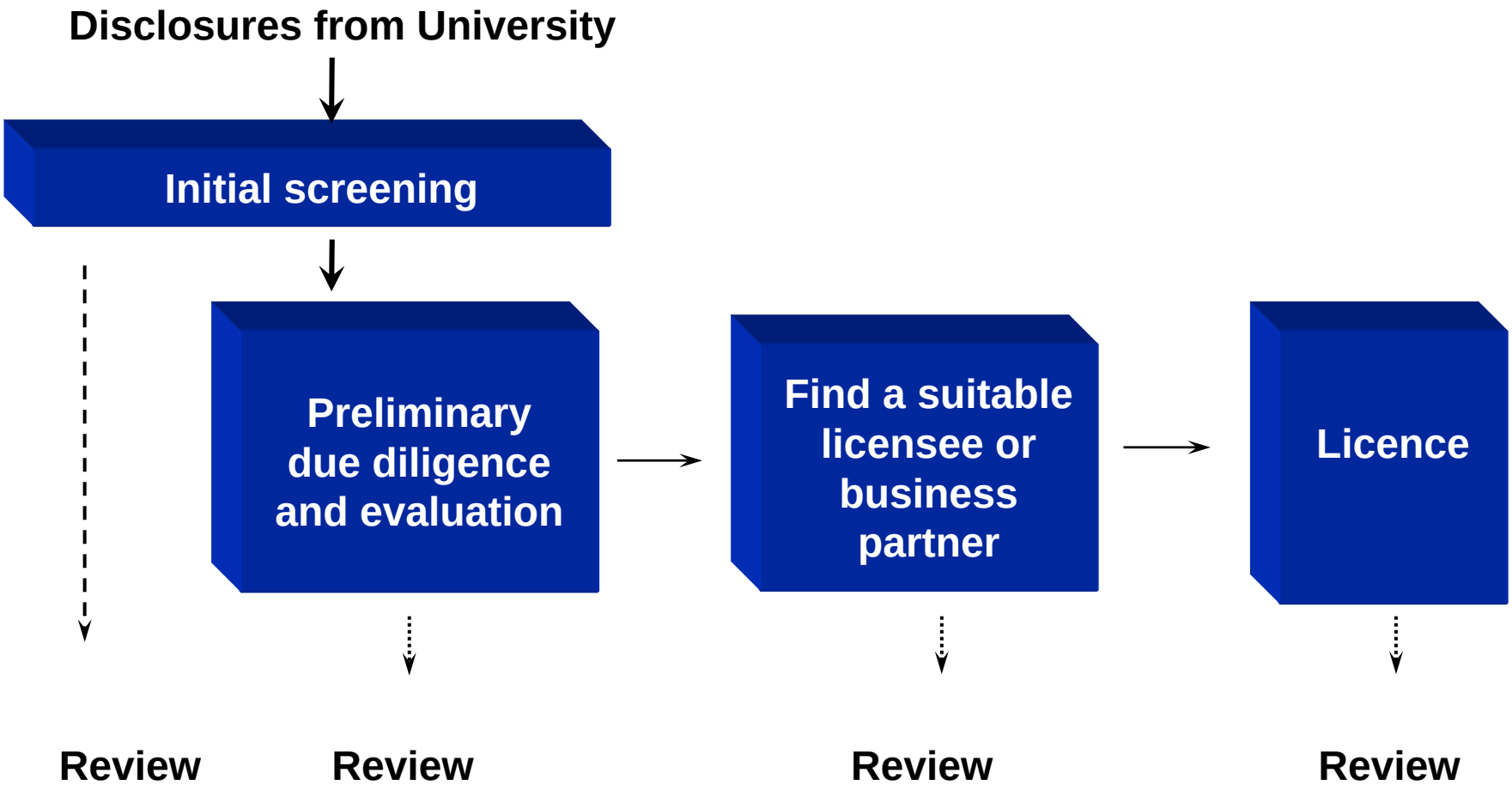
Advantages:

- Acquire new technology
- Avoid research costs
- If product is proven, risk is reduced
- Quick and easy way to diversify

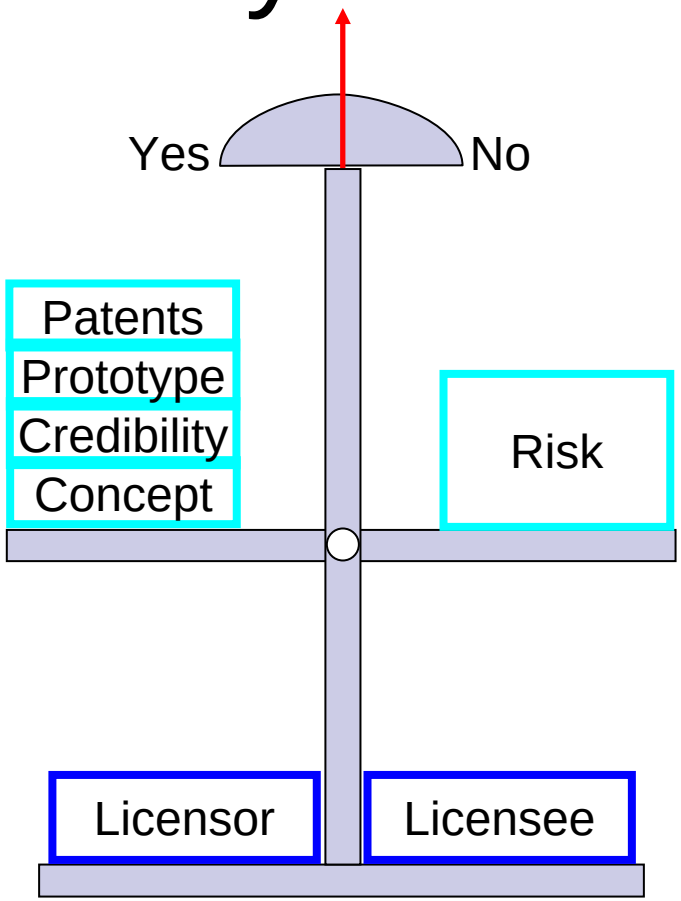
Disadvantages:

- Licence may restrict ability to expand and develop
- Royalty may be greater than profit
- Product liability

The conventional university technology licensing process



How much do you licene for?



Slide courtesy Dr Mark Horsburgh FAK Patent Attorneys

To consider when licensing:

- Exclusive/non exclusive
- Field, Territory of use, Term
- Performance requirements
- Returns via
  - Royalties (% of product sales)
  - Milestone payments
  - Annual maintenance fees
  - % of sub-licence fees
- Leverage for research funding
- Retention of research rights
- Warranties
- Termination

Due diligence

- Is this the right licensee? Are they financially sound? Able to take the technology to market?
- Am I talking to the right person in the company?
- How motivated is the potential licensee to deal? (strategy, size, recent performance, etc)
- What are the licensee's likely deal criteria? (market size)
- Would the licensee fight to protect my patent?
- What are my deal criteria & my overall strategy?
- What is the industry benchmark for this kind of deal?

The start-up pathway

Why form a start-up?

- Allows investment to fund R&D and commercialisation
- Potential for greater return on your research
- Greater involvement/ voice in the process
- University and driver(s) obtain rights to returns from equity (shares) and/or royalties

Risk

- A start-up is a high risk:
  - Research, market, human, financial
  - Always risk that no-one will invest, research falls over, make a lot less than expected, will have to cede more control to investors
- Higher management & workload
- Corporate governance
- Taxation consequences

Start-ups resourced by:

- Private investors / angels
- Seed capital / venture capital
- Licence/assignment of IP
- Research funding and close relationship with University research team

Most common types of start-ups

Technology Development

- Unique technology/ intellectual property
- Technology under development
- Little or no revenues
- Funding required

Business Expansion

- Operating business within parent entity
- Revenues, cashflow and profits in most cases
- Opportunity for growth
- Typically services IT or small manufacturing business

People involved in a start-up

- Founders/ Inventors/ Research team
- Board of Directors
- Commercial/ management expertise
- Shareholders/ Investors

Essential to a successful start-up

- Sufficient & timely funding
- Thorough market research
- Clear business development strategy
- Capability in all areas (at right time)
- Experience in critical areas
- Meet milestones on time
- Shared team view
- Understand and manage risk at all levels
- A product

When securing investment keep in mind:

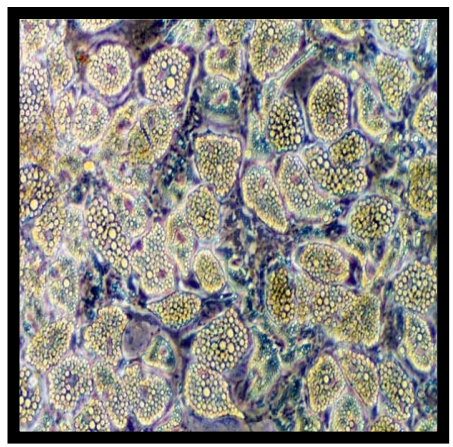
- the fewer investors the better
- communication
- understand investor perspectives/requirements
- deal with dilution and loss of control

Workgroup Session 3

Case study: Adipogen Pty Ltd

Discovery

- Known growth factor causes fibroblast cells to grow and become fat cells = a new use
- Researcher planned only to publish results



Recognition of value

- Inhibition of the growth factor may reduce fat accumulation in people
- Inhibitors known, but not for this use = patentable invention

Commercial Assessment

- Market: Multi-Billion and growing
- Technology: Early stage, but novel
- Competitors: Clear need for new drugs
- People: Leader in field, commercially aware

Commercialisation

- New company formed with pre-seed investment from VC
- R&D to select best inhibitor and enable patents
- Negotiations with pharmaceutical companies

Case study: Digital Core Laboratories

- Analyses the physical properties of rock cores for presence of oil and other factors of interest
- Uses digital imaging rather than direct physical measurement of properties

- Nine inventors from Applied Mathematics, RSPhysE
- One inventor from UNSW
- Opportunity grew from an industry-based research consortium, involving over ten global oil companies
- IP developed:
- Hardware (micro CT-scanner)
- Software (to reconstruct images from the micro CT-scanner)

Case study: Digital Core Laboratories

- Digital analysis technique has been compared with traditional lab-based techniques
- Digital technology has comparable performance, at a fraction of the time / cost : this is where the value lies.

- Opportunity to form a services-based starup company – DCL Pty Ltd was formed in January 2008
- DCL will analyse rock cores provided by clients

- Inventors issued shares – totalling 40% of equity
- Remaining ownership split between ANU and UNSW

Case study: Digital Core Laboratories

- Licence agreement has been finalised earlier this year – allowing **DCL** to use **ANU**-owned Intellectual Property

- Company is based at RSPhysE – several researchers are working full or part-time in the company.

- Currently servicing orders from several companies.