L2: Biotechnology as a Business

The term biotechnology was first used by Karl Ereky in his book 'Biotechnology of Meat, Fat and Milk Production in 1919'

- The book deals with animal production using sugar beets as a food source (converting raw materials into a more useful products)
- In 1919 there was wide-spread famine and shortages post-war in Hungary
- Ereky was a minister for food with an engineering background
- He set up fattening centres where 100,000 pigs/year converted sugar beets into lard and sausages.
    - This was his solution to food shortages
    - Pigs were 'biotechnology machines'

Biotechnology revolutions are an ongoing part of human history

- Ancient biotechnology
    - Agriculture and selective breeding
    - Fermentation
        - 10,000 years ago
- Classical biotechnology
    - Louis Pasteur and industrial fermentations
        - 150 years ago
- Genetic engineering
        - 40 years ago

Societies are dependent on biotechnology for food production and food security, thus maintaining and advancing society. But:

New biotechnologies are often controversial because they raise ethical issues. They become the subject of public debate because people are wary of doing things that haven't been done before as they are unsure of possible future effects. However, public debate raises the issues and presents different viewpoints which enables informed decisions and also influences government organisations that control new research and development.

Modern Biotechnology Revolution

In 1945, President Roosevelt asked Vannevar Bush (an engineer and researcher during WWII) to come up with a plan to improve national welfare and maintain scientific and technical superiority. The Bush report 'Science: The Endless Frontier' argued the government funding of science, published in July 1945. Two weeks later, the bombing of Hiroshima occurs and WW2 is ended, which is clear demonstration of the power of science and the need to control knowledge.

Basic Biotechnology Strategy 1

- Driven by investment
- Investment is money and time spent now in the hope of a future benefit (ROI)
- **A Return on Investment (ROI) measures the gain or loss generated on an investment relative to the amount of money invested.** A high ROI means the investment's gains compare favourable to its cost.

The government gives money to scientific bodies such as The National Health and Medical Research Council (NHMRC) and The Australian Research Council (ARC). This money is distributed based on competitive grants. Money is given to the universities in order for them to conduct research. The universities must report back on their findings. Capital **is wealth in the form of money or other assets owned by a person or organisation** or available for a purpose such as starting a company or investing. Scientific capital **is the level of exposure and knowledge of science-related things.** That is, doing research increases our scientific capital by increasing our knowledge. We then need to patent these new findings and publish them too. We can then create new jobs which means that we pay tax which goes back to the government and then the money gets distributed all over again.

The Bayh-Dole Act

The Bayh-Dole Act **– to encourage the utilisation of inventions produced under US government funding by giving clear IP rights to universities.**

- A lot of scientific capital gets stuck in universities and this is addressed by the B-D act.
- The Act or Patent and Trademark Law Amendments Act was passed in 1980 in US (no similar act in Australia).
- Universities are expected to file for patent protection and ensure commercialisation upon licensing.
    - Universities that receive federal funding can choose to pursue ownership of their invention rather than assigning the invention to the government.
- University Technology Transfer Offices (TTO) **were established to help encourage universities to develop inventions and turn basic research into applied research and commercialisation.**

The Cohen-Boyer paper

- In 1973, Stan Cohen and Herbert Boyer published a scientific paper
- It shows that a plasmid and a DNA molecule of interest can be cut with a restriction enzyme and ligated together to make a recombinant plasmid
- The patent was submitted in 1974 and was issued in 1980 to Stanford University
- It was controversial as they weren't sure if you could patent a living organism/process
- By the time the patent expired in 1997:
    - 468 companies had licensed it in order to use it
        - 2442 new products
        - $35b in sales
        - $255m for Stanford

Genentech

- In 1976, Boyer and Robert Swanson established Genentech, the world's first biotech company
- Genentech shares were first offered to the public in 1980.
- They started to **exploit recombinant DNA tech.**
- Stanford Uni made $255m from the licensing of 3 Gene Splicing patents by Cohen & Boyer
- The licensing extracted significant value from this technology and facilitated the birth of the biotech industry
- **There were non-exclusive licenses, small upfront licensing fees and small % royalties on products developed using the technology**
- The licensee only had to pay if and when it got a product on the market
- It is easy to get companies to sign up for these licenses.
- **A licensing strategy is adopted by many companies**
    - **To attract investors**
    - **To broaden the application of the product or technology**
    - **To bring returns on investment**

Government funding

The Government gives grants to universities and also gives money to National Funding Bodies such as the Australian Research Council and the National Health & Medical Research Council. This money is then distributed to Academic Researchers and hopefully generates new knowledge in the form of publications and highly skilled individuals which will then generate money for the government.

Universities collaborate with industry companies to enhance innovation through knowledge exchange. Universities undergo curiosity-driven research and skunk works – a project developed by a relatively small and loosely structured group of people who research and develop an idea primarily for the sake of innovation. The companies need to, however, have a return of investment and aim to commercialise a product. There is an unclear boundary between the two – some companies and some researchers are in direct contact with each other but others are not.

Technology Transfer

TTOs

The Bayh-Dole Act encouraged universities to develop their inventions. Technology Transfer Offices (TTOs) were established to help do this. TTOs **identify research which has a potential interest and develop strategies for how to exploit it.** A consideration of this is the commercial value of the invention. The process to commercially exploit research varies. It can involve licensing agreements or setting up partnerships to share the risks and rewards of commercialisation.

Spin outs **are used when the host organisation does not have the necessary will, resources or skills to develop a new technology.** These approaches involve the raising of venture capital as a means of funding the development process.

TTOs **may work on behalf of research institutions and where start-ups and spin-outs are involved, and commercial fees can be waived in lieu of an equity in the business.** TTOs include economists, lawyers, marketers and scientists. TTOs also review academic research to look for partner companies.

Some companies are in the right place at the right time with their existing research and development to address immediate demands. They can respond quickly to health emergencies by adapting their technologies to generate therapeutics or vaccines. This was evident during the SARS and Ebola outbreaks and will be evident during COVID-19.

L3: Technology Transfer in the University Sector

TTOs assist the academic community to safeguard and translate the intellectual property generated through the university's research and development for social, environmental and economic impact. They transform ideas and creations into reality.

Evidence drives the potential for investment. Investors also take into consideration whether a company's competitors are likely to develop a similar product first. Few biotech companies make a profit (90% don't), due considerably to the time it takes to commercialise a product. If they run out of money, they may have to consider selling the technology to keep going.
Without a patent, you don't get much money from investors. A patent strategy adds value to an institution, and they can add additional patents for longevity of the protection.

Knowledge and technology transfer is the transfer of knowledge and discoveries to the broader community through:

- Publications
- Educated students entering the workforce
- Exchanges at conferences
- Relationships with industry and government
- Formal licensing of intellectual property created by University researched to third parties who exploit its commercial value and other benefits.

The Technology Commercialisation Cycle

- **Research**
  Discoveries are made and IP is created through research activities
- **Pre Disclosure**
  Initial contact with Research, Innovation and Commercialisation, Business Development & Technology Transfer teams to discuss the IP
- **IP Disclosure**
  Submission of the completed IP disclosure form for RIC to evaluate
- **Assessment**
  Review of the disclosure, patent searches, analysis of market and competitive technologies in order to determine the commercialisation potential (continued below)
- **IP Protection**
  This is provided via patents (if applicable)
- **Marketing**
  Identification of candidate companies that have the expertise, resources and business networks to bring the technology to market
- **Licensing**
  University IP rights are licensed to an existing company, start-up or spin-out
- **Commercialisation**
  Licensee develops commercial products or services based on the technology
- **Revenue Distribution**
  Licensee payments to the University are shared internally
- **Reinvestment**

Funds received by the university and faculties are reinvested to support further research and education

Technology Transfer Process

Invention Disclosure

- **Invention disclosure form (IDF) – collects info about a university invention**
    - What is the problem
    - What is the solution
    - Where is the funding coming from
- Must have some sort of commercialisation route, and a problem that can be solved, not just scientific curiosity

Access

- **Invention assessment – review key factors and considerations to determine whether an invention should be commercialised**
- Ownership of the IP
    - Who created the invention?
    - Where do they work and who owns it?
    - Does UoM have permission to commercialise the IP of the collaborators?
- Technical Analysis
    - What stage of development is it at?
    - What resources are needed to further develop it?
    - Technology readiness levels: TRL 1 – 9 where 9 is most mature
        - NASA developed this
    - Universities typically develop up to stage 3 then industry is required beyond here
- IP analysis
    - Is there any IP underpinning the disclosed technology which can be commercialised?
    - Is it patentable?
- Market analysis
    - Market need
    - Competitive advantage
    - Market size and value
    - Commercialisation route

Protect

- **Protecting technology – acquire IP rights to be able to protect the IP required to commercialise**

Commercialise

- **University IP may be commercialised by licensing the IP to an established industry or by creating a spin-out company**
- Commercialisation through IP licensing
    - IP remains owned by uni
    - Licensee responsible for developing and selling product
    - Uni receives payments for the grant
    - Low risk and hands off