Marine Genetic Resources

Commercialisation: Not Plain Sailing

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Scope and Purpose of Presentation

- Show some of the complexities of Commercialisation from two perspectives - the discoverer & the developer
- Relationship between public and private research - the 3 Waves of change
- Market failure - transfer of risk,
- Risk management along the development chain: the dos and don’ts
- Removal of impediments
- 3 ideas for national governments

Setting the scene: MGR - Who is doing the work? - Old paradigm

Public research bodies

- Institutes, Museums, University Sector

Private sector

- Large chemical
- Large Pharmaceutical
- Plus beginnings of Biotech enterprises

Setting the scene: 1980 1st Wave of Change - US Bayh Dole Act

- Publicly funded institutions encouraged to capture the economic value of their research through the patent system
- Progressive adoption of the concept around world
- Confusion between commercial and non-commercial research
- Difficult to deal with serendipetous commercial discovery

Setting the scene: Who is doing the work now?

Both Public **and** Private research bodies

- National research institutes
- University Sector
- Biotech companies - usually small to medium start-up companies
- A limited number of vertically integrated pharmaceutical companies
- Joint public/private ventures

Commercialisation - the 2nd Wave

Recombinant Chemistry:

- over the last 20 years the pharmaceutical industry invested heavily on recombinant chemistry as the dominant source of new drugs.
- Appeared to be easier than trying to create analogues of natural compounds
- Avoided possible access issues
- Reduction in field work by major pharmaceuticals
- Disaster - Produced only 1 significant new drug*.

The 3rd Wave: new pharma business case in response

- Seek economies of scale via mergers
- Invest in or purchase successful biotechs
- Extend old patents (ever-greening)
- Find new uses and new markets for existing drugs
- Transfer biodiscovery risk to public sector and biotechs
- Pay strict attention to due dilligence

Consequences for Biodiscovery

- Commercialisation of MGR now largely in the hands of specialised biotechnology companies and publicly funded bodies: usually both lack capital
- A complex, inefficient development chain is created in consequence
- High casualty rate among start-up companies
- High transaction costs - with Public bodies unable to offset costs against revenue streams

Commercialisation strategy

Small companies & public institutions doing MGR research respond by:

- entering into biodiscovery partnerships and consortia
- Following shifting patterns of investment eg demand for biofuels, enzymes, nutraceuticals
- Understanding the due diligence needs of investors/major companies

Due diligence - managing legal and commercial risk

- Collect samples in areas which provide, legal certainty and verification
- Collect in areas where reliable taxonomic services can be obtained
- Avoid premature publication of research
- Avoid premature application for IP
- Understand differing IP requirements of target markets
- Remember inconsistent taxonomy can destroy or damage the value of IP*

Meeting due diligence

- Avoid engaging partners whose reputation may pose risks to investors' shareholder value.
- Ensure capital support is sufficient to develop the product to the point that an investor is likely to take it to approval and registration and will actively market it.*
- For high value products its very likely that the due diligence will be undertaken by a foreign firm unfamiliar with local conditions

Removing impediments - Role of Governments

National Governments can realistically improve the efficiency of the commercialisation process by:

- Providing legal certainty through CBD based ABS systems
- Investing in their marine taxonomy - this assists both research efficiency and produces stronger IP
- Supporting international initiatives such as the Census of Marine Life

Removing impediments - Role of Governments

Address current market failure by:

- Adequately funding public research bodies to support their efficient operation or
- Creating public/private consortia such as the Western Australian Marine Science Institute WAMSI

Removing impediments - Role of Governments

Address market failure by:

- Realistic expectations - Understanding no matter what the long-term outcome, the immediate, certain and tangible benefits of biodiscovery lie in improved scientific knowledge of marine organisms and their interactions
- Consider merit-based access to capital for small companies to take development beyond proof of concept to being investment ready.

Additional views on Priorities

Professor Snow Barlow, immediate past President of the the Federation of Australian Scientific and and Technological societies:

- Support taxonomic initiatives (like the Atlas of Living Australia) - taxonomy is the foundation for meaningful biological research

Additional views on Priorities

Nick Falk, Maranova Business Development Manager:

- Provide legal certainty and keep regulatory costs and burdens low
- Few government supported institutions share data and research well - a lot of time is wasted replicating early stage genetic and component analysis.
- any group depending on government funding should be required to share data that does not counteract its competitive research advantage.

Summary and conclusion

- Biotechnology is replacing Pharmaceuticals as the driver for commercial research on MGR
- Meeting due diligence requirements is necessary for partners to decide to invest in new product development and marketing
- Due diligence is a market tool against biopiracy
- Governments can support commercialisation by providing legal certainty and a reliable taxonomy