

Abstract

Commercialisation: Not Plain Sailing

Geoff Burton

Principal Consultant Genetic Resources Management

Jean Shannon and Associates Pty Ltd (geoff@jeanshannon.com)

This presentation will identify the actors in the commercialisation process, how they interact, the challenges facing them and the symbiotic relationship between public and private research on marine genetic resources. It will identify the changing business investment case being driven by responses to uncertainty and the desire to transfer risk down the commercial development chain. The presentation will identify key risk factors. The interaction between the national interest in publicly funded research, the conservation of marine genetic resources and the creation of opportunities for science-based industry have led some governments to identify obstacles to commercialisation. The presentation will provide cases and possible initiatives that may be considered to remove impediments.

The range of bodies conducting research and seeking to commercialise their research has been broadened by the application of the US Bayh Dole intellectual property utilisation reforms to include university systems and publicly funded research bodies. Whether by serendipitous discovery, or through directed research, commercially valuable discoveries will be commercialised. This trend is not reversible. Universities are now sources of new start-up companies. This fact, coupled with the recent explosion in biotechnology investment means that the commercialisation of marine genetic resources is now in the hands of small, specialised biotechnology companies and publicly funded research institutions. Neither commonly have the resources to develop their discoveries to market. They must seek either additional capital or partnerships. This is an uncertain and risky process with a high casualty rate. To succeed in commercialisation, biodiscoverers must understand the needs of their future partners in the development chain. Early mistakes preclude later success. For example premature publication of research may damage the creation of intellectual property (IP). Poor taxonomy of the marine source organism may destroy IP. Failure to consider the differing requirements of national IP systems may weaken their IP or damage its market value. Poor investment in sound contractual practices in the early stages of development may result in legal uncertainty.

Companies must have regard to the due diligence needs of future investors and partners. Lack of clarity over the origins of marine genetic resources collected for biodiscovery, its identity, legal obligations associated with its collection and public perceptions about the circumstances of its collection, all have the potential to damage share-holder value or to raise legal uncertainty. Companies and investors protect their interests by associating with bodies that have addressed these issues at the outset. The higher the cost of development: the greater sensitivity to risk. Vertically integrated companies, such as pharmaceutical companies, increasingly transfer risk by buying into the product development chain when due diligence demonstrates risk is low and commercial success is likely - bearing in mind that 50% of candidate drugs

fail at phase 3 clinical trials. Another sort of risk occurs when marine research bodies and biotechnology companies fail to attract enough development capital to reach the stage where commercial partners are interested. This is a problem for small companies in developed countries and a larger problem for companies and marine research bodies in developing and rapidly developing countries.

Some government intervention can improve the efficiency of the commercialisation process. For example, investing in better national marine taxonomy improves the chances of biodiscovery, creates more robust IP and assists in deriving benefits from understanding polymorphism and symbiotic organisms and their proteomic responses to stressors. National investments such as Australia's *Atlas of Living Australia* and support for international taxonomic initiatives such as the *Census of Marine Life*, the *Global Taxonomic Initiative* and more recently, the *Encyclopaedia of Life* together with the marriage of molecular taxonomy with morphological taxonomy has the capacity to accelerate biodiscovery by reducing costs and increasing certainty. National action for facilitated access to marine living resources and legal certainty for their collection eliminates another obstacle and creates a transparent pathway for benefit-sharing and good conservation outcomes. Addressing market failure by better public funding of marine research and merit-based access to capital for small biotechnology companies developing products beyond proof-of-concept stage to being commercial ready are other initiatives to be considered.
