C:\Documents and Settings\nathr\Local Settings\Temporary Internet Files\OLK41\Intellectual Property and Patents.doc

### **Pathways to Commercialisation**

The path to profitability is a long one in the biotech industry. It is not uncommon for more than a decade to elapse between initial invention and products in market. Therefore, pathways to commercialization need to be developed with Asian style horizons (ie decades). The way that the Australian biotech industry is configured, this is almost impossible. Proteome Systems' experience of its instrumentation developments (Xcise and ChIP) is a sobering example of the challenges of limited time horizons. The initial intellectual property was developed at Macquarie University prior to the formation of Proteome Systems. Proteome Systems acquired the IP and partnered the development with Shimadzu, a Japanese instrument company, with support from an Australian Government START Grant, The Initial development and early prototyping was accomplished successfully with support from START but after this stage, when the process becomes expensive, Government support evaporated and it became extremely difficult to complete the commercialization. Our Japanese partner sits patiently waiting to acquire the products when Proteome Systems runs out of cash to complete the commercialization. The likely outcome is that Proteome Systems will not have the resources to go through the next 3-4 years of establishing the instruments in the global markets. So, it is likely to have to accept a smaller reward despite the fact that it took the product through all of the risky phases of development. This is not the best way to generate long-term wealth.

h

In the pharmaceutical area, a similar situation applies except that the out-licensing occurs much earlier in the productisation because of the expense of taking a drug to market. Australia is building the infrastructure (eg clinical trial capacity, manufacturing etc) to take a drug to market. It needs courage and capital to make it possible.

## **Intellectual Property and Patents**

The biotechnology industry has very long timeframes and hence, it is important to establish value on the path to profit. One means for doing this that is well established in the industry is to protect inventions through patenting. Most companies on the US NASDAQ stock Exchange are not yet profitable and have been able to build substantial market capitalization based on their intellectual property portfolios (ie indicators of expected future profitability). The early stages of patenting are very cheap but the strategy of building an intellectual property portfolio is a little like building a picket fence. Initially one establishes the corner posts, but these need to be filled in with additional protection. This is in the form of both offensive and defensive patents. It is not difficult in building a significant patent portfolio to incur costs in the order of \$1million per year. The way that the Australian Biotech industry is capitalized, such a portfolio is almost impossible to assemble. Indeed, of Australia biotech/device companies, ResMed, Cochlear and CSL may be the only groups able to afford this. To establish value and be able to use to springboard into profitable businesses, there needs to be a means for affordably building strong patent portfolios. Currently this does not exist in Australia.

#### **Skills and Business Knowledge**

Australia is currently quite well served with skilled scientists/technologists and business people with experience in technology companies. The challenge is for technology companies having sufficient capital and momentum to afford quality people.

#### **Capital and Risk Investment**

This remains a major deficit. There is a huge need for more patient capital that is required for the long development periods in the biotechnology industry in particular.

C:\Documents and Settings\nathr\Local Settings\Temporary Internet Files\OLK41\Intellectual Property and Patents.doc

## **Research and Market Linkages**

Australians have a tradition of travel and in general, they are well connected to the world. This is increasingly true of our connections with Asia although in the biotech industry, these linkages seem often to be underexploited because of an obsession with the US markets. In Proteome Systems, we have focused particularly on the Japanese market and more recently we have begun to focus on China and India where large opportunities are emerging.

## Factors determining success

A critical issue for Proteome Systems has been the difficulty of getting our products sold in our home market. There is still a well established "not invented here" syndrome. There is also a reluctance to purchase technology products from a young Australian company. This leads to two problems. Firstly servicing our own markets is much easier than servicing export markets and so there is the possibility of low hanging fruit with customers with whom we can interact easily. Secondly, the absence of penetration of our local market is a serious disadvantage in seeking to enter Asian markets where there is an expectation that our products should be well accepted at home. Currently there is no incentive to buy local and indeed, our global competitors exploit the fact that Australian purchasers often go to the lowest tender regardless of whether that tender offer is the best value. In other words, intangibles, such as accessing a local support structure are disregarded in purchasing decisions. Regardless of geography, success is largely a matter of persistence and staying alive

den strange

. or which the little little is a second sec

# Strategies in other countries that may be of instruction to Australia

The process of commercialization is an expensive and slow process. In the US there is a well established grant structure for small companies to assist them beyond the development stage. Indeed, many small US companies stay alive with assistance from US Government grants. There is no comparable support in the Australian scene.