Intellectual Property Strategy and Business Strategy: Connections through Innovation Strategy

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(Including case studies by

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Introduction

There has been increasing attention given to the active management of intellectual property in recent years, both by practicing managers and researchers. This growth in emphasis has occurred as we have seen organisations increasingly move towards being bundles of knowledge, with intangible assets, principally knowledge, often being significantly more valuable than tangible assets.

Miles and Snow (1978) suggested that organisations that innovate will be superior in their profit and growth performance. Innovation processes can be directed towards any or all of the following domains: Process, Products, Competitive Position and Business Model. Process innovation can be thought of in terms of technological improvements such as new machinery or new computing hardware or software that undertakes the value adding processes in an organisation. Product innovation can be incremental or radical and involves in some way changing, and hopefully improving, the value of the offering that is made to the customer. Product innovation includes goods and services. Competitive position innovation may mean changing the market segment in which a company operates such as moving up the market or down the market or changing from one order-winning criterion to another. Business Model innovation can mean a development and implementation of a new business model, such as Dell Computers' Dell Direct approach, or it can be a significant change to the soft variables of an organisation such as its culture or values (Francis, 1998).

Business Strategy as the Overall Framework within which IP is Managed

An organisation's business strategy involves setting the overall direction of the company, its goals and performance metrics, and arranging for the resources with which to achieve that strategy. Business strategy includes marketing elements involving the products and services specification and the positioning of those in the

market place. Business strategy also has resource specific aspects such as the degree to which insourcing versus outsourcing will be undertaken within the value creating processes of the organisation. There is also, as a part of business strategy, the structural and ownership elements of the firm, as well as the financial strategies, such as whether to hedge currencies or not, setting debt to equity ratios and a variety of other financial variables. It is clear that a business strategy must successfully integrate these various aspects such that they are aligned and synergistically take the organisation towards its desired goals.

A sound business strategy also positions the organisation well in terms of its external environment, namely the set of external pressures and opportunities facing the firm including market forces, government regulation, and all other significant stakeholder relationships. Indeed business strategy can be seen as fitting the functional policy settings together as well as fitting them collectively to the environment and its pressures such as to develop and maximise the leverage that is possible from the organisation's capabilities.

Business Strategy and Innovation

Innovation need not be a major or dominant part of all firms' business strategy. For some firms, for example in pure commodity industries, innovation in some form of differentiated offering or activity may not be important. The only important strategy may be the achievement of the lowest cost of production of such commodities. However for most organisations, innovation is indeed important, especially if it is defined as broadly as containing the aspects of products, processes, paradigms (business models) and positioning.

Innovation strategy, which can be considered as the plan of how the organisation will create value through new activities in any of the four domains above, can be considered as a subset of business strategy. However a firms' innovation strategy is far from all of its business strategy. Innovation strategy, as a subset of business strategy, therefore must be guided by the firms overall business strategy. In return, an innovation strategy can give real power to the business strategy.

Intellectual Property (IP) and Innovation

An organisation's intellectual property can be considered as its specifically owned knowledge assets that are not owned by any other firm or organisation. For firms that make investments in developing new products and services, processes, paradigms, or specific market positions that are unique, a return on these investments is a reasonable expectation. There is risk in making these investments and shareholders and other stakeholders will expect a return that is at least commensurate with this risk.

There are many tactics that an organisation can employ to attempt to increase the return that it gets from investments in innovation, such as keeping the innovative process technologies that it has developed a secret. An example is the chemical process associated with making a pharmaceutical, or perhaps the core code of a software package that is sold in a marketplace. Keeping these secret provides exclusivity, reduces total supply and hence provides higher market share and higher prices than if the information was openly published.

Another intellectual property protection strategy is to disclose in part the nature of the knowledge asset through patenting. This is quite the opposite of keeping it secret in the sense that one publishes enough of the information such as to describe it comprehensively and publicly claim the ownership of that knowledge. The return can then come from restricting the supply of goods and services that require that knowledge to be produced and/or licensing out that knowledge or technologies or products to others that make use of it.

The central thesis of this argument is that the essence of strategy as applied to any asset in an organisation is not only the value of that asset on its own, but much more the value of that asset as it contributes to the whole of the organisation which can be considered a set of assets, both tangible and intangible. Generally this is the essence of what is meant by strategy. A marketing strategy is typically more valuable if it is well matched to an operations strategy than if it is not well matched, and vice versa. We would argue then that as shown in Figure 1, an IP strategy should be well matched to a complete innovation strategy, which in turn should be well matched to the complete business strategy of the organisation. This is indeed the essence of what

makes for an IP strategy, as without these connections and synergies we have only IP tactics and IP decisions and resource allocations.

Figure 1 about here

In this paper we further examine the relationships between business strategy, innovation strategy and intellectual property strategy and illustrate these via case studies.

Review of the Literature

According to Alpert (1993) “Innovations are the lifeblood of our economic system”. Alpert is critical of intellectual property law, which he says has not changed much in the past 200 years despite the increasing challenges and importance of innovation in firms. Alpert argues that the cost of developing and introducing a major new product has jumped to be over US$100 million. These costs relate to product development, market research, process development and launch costs. Alpert’s central argument is that patent boundaries as set by regulators are too narrow and thus fail to provide enough motivation for firms to optimally invest in creative or innovative activities.

A key question is the extent to which an innovation must be different from that which exists in order to comprise new and distinct intellectual property. According to Alpert, “One useful answer is that a product is the application of a distinct technology to the provision of a particular function for a specific customer good. Only when a change occurs along one or more of these dimensions which involves a sharp departure from the present strategies of participating competitors is a separate life cycle necessary”. This could indeed be considered as a basis for defining where new intellectual property has been created, namely a significant departure of technology or function or customer group.

In considering the relationship between business strategy and innovation activities, Mecand et al (2001) conducted a survey of 231 family businesses. They characterised strategy using the Miles and Snow methodology such that firms are *either defenders, analysers, reactors or prospectors*. They found interesting relationships between size

of business and strategy such that prospectors were more likely to be smaller and younger businesses. Prospectors engaged in significantly more new product and service development and graded themselves higher in terms of strategic planning and in ensuring adequate resources for their growth than did non-prospector firms. This immediately establishes a connection, at least within this context, between business strategy and innovation strategy. Prospector firms also had greater emphasis on mission statements, regularly scheduled board meetings and other organisational disciplines, despite the fact that prospector firms were more likely to be smaller and younger. Prospector firms also made significantly higher investments in human resource elements of strategy such as training and career development.

Affuah (1999) has coined the terms *blocking, running and teaming up* as generic strategies, which he says integrate with a firm's competencies and its assets. Are these innovation strategies or business strategies? The answer is that they lie right at the heart of the interface between innovation strategies and more generic business strategies. Affuah asks the question, "How do firms protect their profits?" Blocking is defined as having two mechanisms, namely the limitation of access to its unique and inimitable assets (such as IP that is protected, and through its market or asset position). Affuah argues that blocking can only work for a limited amount of time, and that ultimately patent barriers or other forms of barriers to entry will be overcome by competitors. Affuah's 'running' strategy argues that sitting behind blockades makes a firm a sitting duck for competitors to catch up and indeed leap frog, and that the innovator should run rather than block. It should be noted that the IP strategy associated with an innovation strategy of running would be entirely different to that of blocking. One mostly involves secrecy (which would generally be associated with running) whereas the other involves patenting (a generic blocking strategy). Affuah's 'teaming up strategy' involves encouraging entry into the industry or product segment by competitors for the purpose of possibly achieving a dominant design, increasing market size, or accessing markets by the achievement of some other form of scale which comes from encouraging growth. Consider IBM in its PC introduction in which it opened its architecture to encourage growth of its dominant PC design whereas Apple computers attempted a blocking strategy during that same period which severely limited the application of the Macintosh. The three generic strategies of

blocking, running and teaming up are suggested by Affuah to also be a function of competency of the firm and its position in the business environment.

Wagman and Scofield (1999) have defined intellectual property as "Physical manifestation of original thought in compliance with statutes, specifically patent, copyright or trademark statutes". Wagman and Scofield illustrate that ever since the first known patent, in 1421 in the Republic of Florence, there has been a strong connection between intellectual property, innovation strategy and business strategy, and its profitability outcomes. This very first patent, related to a ship on the Arno River in Florence, which could more effectively and/or more cheaply allow goods to be loaded on the river. The authors argue that the intellectual property that was granted by the patent was to provide to the inventor "Temporary monopolistic control over… the fruits of, their own efforts". Intellectual property strategies, whether to patent or otherwise, aimed to provide the inventor with the fruits of commercialisation and innovation and to therefore stimulate business strategies of this type.

Wagman and Scofield (1999) suggest that "It is difficult for intellectual property laws to keep pace with technology". The authors claim that in 1993, some US$23 billion was lost because of intellectual property infringement to US industries. They point to the ongoing problem that in developing countries, the theft of intellectual property is widespread. The effectiveness of IP protection laws and frameworks will impact of the relative attractiveness of running vs blocking vs teaming up strategies and would therefore be expected to be different in industries such as computing and software and entertainment (where IP theft is rampant) than in the construction industry where IP theft is much less extensive.

Heller and Eisenberg (1998) argue that "The recent proliferation of intellectual property rights in biomedical research suggests a different tragedy (from the tragedy of the commons), an 'anti-commons' in which people under-use scarce resources because too many owners can block each other. This is an effect that is opposite to that of teaming up (Affuah, 1999). Heller and Eisenberg argue that more intellectual property rights may lead paradoxically to less progress in developing biomedical products, which is opposite to the desired result in society at large. This is because of the scattering and lack of inter-firm synergies that will occur through strong forms of

protection that lead to high barriers to information flow and/or to more secrecy. To amplify this point from a value chain perspective, Heller and Eisenberg point out that: "Proliferation of intellectual property rights upstream can stifle product development downstream in biotechnology applications".

Spinello (2003) argues that intellectual property protection is being expanded in scope and that this threatens technologies such as the internet, restricting innovation in and the capability of the internet. Further he suggests that "Copyright law is both too complicated and too restrictive". The argument is that creativity is stifled in the large and that the "Intellectual commons is in jeopardy". The issue is clearly that of achieving a balance between the right of the individual and the common good.

In an empirical study, Magee and Dowling (1994) found relationships and indeed interactive effects "Between investments in innovation and competitive strategies and performance". Dowling and Magee bring clarity to the linkage between business strategy, innovation strategy and intellectual property strategies by pointing to the concept of "strategic timing" which involves choices as to whether to be a first or second mover. Others have called these ideas that of being a technological leader or follower. Sony's business strategy, for example, is that of technological leadership. Their pursuance of first mover advantage leads to innovation strategies of investing in radical new technologies, which are in turn connected to Sony's IP strategy. These are very different to those companies who attempt to follow Sony with lower cost clones.

Roberts (2003) found that the returns to innovation and therefore the efforts made in innovation differ according to economic conditions. Roberts showed that a significantly different percentage of the increasing return on capital employed occurs for firms during recession and during recovery according to the percentage of sales that comes from new products. Therefore it can be concluded that during a recovery, substantially higher returns are associated with the sales from new products than during a recession in which case percentage sales from new products are relatively low in comparison to the returns associated with firms having low or average percentage sales from new products. Innovators benefit more during recoveries and less during recessions, and this is presumably because of consumer behaviour. Roberts shows that in the first two years of a recovery, sales from new products jump

and that this is related to the product development efforts and the returns to product development during a recovery as compared to that in a recession. The study clearly demonstrates the relationship between the environment of a firm and its business strategy, which is linked to its innovation and IP strategy respectively.

Case studies of business strategy, innovation and IP strategy.
Three detailed case studies are presented of pharmaceutical companies, that use a variety of techniques for blocking, running and teaming up. These are contrasted to the case of Textileco, a manufacturer and importer of home textiles, which has a different business strategy, hence a different innovation strategy and, hence, a different IP strategy.

Whereas the pharmaceutical companies engage substantially in blocking and to some extent teaming up, TextileCo engages purely in running. TextileCo does engage in innovation, such as in new designs and specifications for the products that it makes, imports and sells, however it is clearly a 'runner' when it comes to IP because of:

- the fast cycle times, of product development and sale, especially at the fashion end of its business. Designs in particular are difficult to protect using blocking tactics, and teaming up is rare in Textile industries;
- difficulty in policing or protecting designs, that can be almost copied, or entirely copied by low cost producers;
- the need to keep giving customers 'new' products, meaning new designs;
- the cost of blocking being high, relative to running and relative to the benefits of blocking.

Pharmaceutical companies, on the other hand put vast amounts of resource into product development, and need to get a return for a decade or longer from their successful products, to pay for both the successful and unsuccessful development efforts. The benefits of blocking are relative high for pharmaceuticals. Policing of breaches is easier than for textiles. If pharmaceutical companies used running tactics, then very soon after a successful product development, many new players would be looking to be the low cost manufacturer, so the incentive to develop new chemicals would be very low.

Hence it is possible to see the connection between the types of business strategies employed by firms, their innovation strategies and actions, and their IP strategies and tactics. Product life cycle length, economics of various IP strategies for that firm and industry, and the cost/ benefit dynamics of innovation within the firm and industry are major factors influencing IP strategies. Our case studies suggest that the direction of influence is not simply 'one-way', from business strategy to innovation strategy to IP strategy, but rather that influences are many and various within the elements of figure 1. For example, the IP opportunities in TextileCo and its degree of success in 'running' with its leading products impacts on where it develops its next generation of products, how it focuses its marketing efforts etc. In other words the IP strategy, impacts 'up the tree' to the innovation, business function and overall corporate strategy.

References

Affuah, A., Strategies to Turn Adversity into Profits, Sloan Management Review, Cambridge, Winter, 1999, Vol 40, Issue 2, pp. 99-110

Alpert, F., Breadth of Coverage for Intellectual Property Law: Encouraging Product Innovation by Broadening Protection, The Journal of Product and Brand Management, Santa Barbara, 1993, Vol 2, Issue 2, pp. 5-18.

Heller M., and R. Eisenberg, 1998, Can Patents Deter Innovation? The Anticommons in Biomedical Research , *Science*, Vol 280, Issue 5364, 698-701 , 1 May 1998

Magee, J., and Dowling, M., 1994, Using R&D Cooperative Arrangements to Leverage Managerial Experience , Journal of business Ventures, n9, pp33-48

Miles, R.E. and Snow C.C., 1978, Organisations Strategy, Structure and Process, New York McGraw Hill.

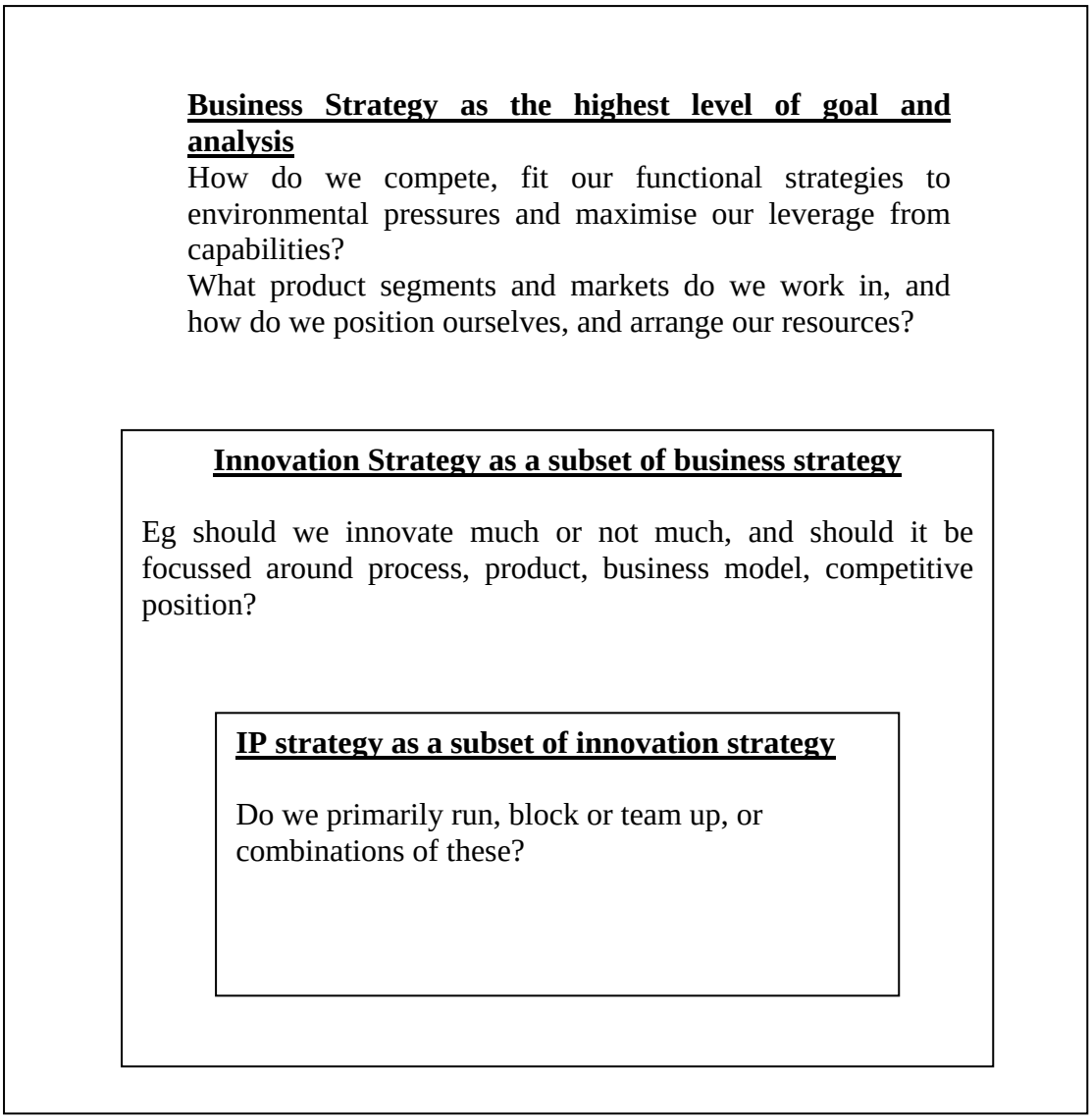
Mecand, J.E., Leon-Guerrero, A and Haley, J.D., Journal of Small Business Management, January 2001, Vol 39, Issue 1, pp. 50-60..

Roberts, K., What Strategic Investments Should You Make During Your Recession to Gain Competitive Advantage in the Recovery, Strategy and Leadership, 2003, Vol 31, Issue 4, pp. 31.

Spinello, R.A., The Future of Intellectual Property, Ethics and Information Technology, 2003, Vol 5, No. 1, pp. 1-16.

Wagman, G. and Scofield, S., The Competitive Advantage of Intellectual Property, SAM Advance Management Journal, Cincinnati, Summer 1999, Vol 64, Issue 3, pp. 4-10.

Figure 1 Business, Innovation and IP Strategies as subsets



Polartechnics[1]

Abstract

The case study provides a qualitative analysis of best practice in intellectual property strategy and commercialisation at Polartechnics Limited. A case study protocol was developed and used to conduct a face-to-face interview with the company's Principal Scientist. Polartechnics core business is to develop and commercialise instrumentation for the screening and detection of normal, pre-cancer and cancer conditions. The case study explores Polartechnics' strategic view and practices around intellectual property by highlighting the strengths and challenges faced by the company in its pursuit of commercial success. The case study sets out the lessons learned.

The Australian Biotechnology Sector

Advances in the broad field of biotechnology are occurring at a rapid rate. Intellectual property presents significant opportunities for commercial exploitation. In business terms intellectual property is commonly regarded as being linked to a firm's competitive advantage. Companies in the Biotechnology sector that are able to sustain competitive advantage and enjoy commercial success have shown that a necessary mix of legal and non-legal mechanisms are required to minimise the risk of losing ownership and control of their creations and the associated commercialisation opportunities.

The driving forces in the biotechnology sector are epitomised by any new drug, instrument or technique that has the potential to significantly change the course of health and living either directly or indirectly. The biotechnology innovation development cycle can be characterized by explorative and rigorous regulatory

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[1] *This case was written by Dr Mile Terziovski and Amy Lai, EACC, University of Melbourne*

elements, where investment in time and resources to achieve a state of market readiness are often large. Intense competition tends to dominate the industry. These conditions combine to elevate the risks of being innovative and increase the uncertainty associated with successful commercialisation.

Generally a firm tries to protect its intellectual property in three ways, by:

- carrying out actions in the product market to prevent competitors from eroding its competitive position through imitation.
- focusing on continuous innovation to prevent imitation and obsolescence. Continuous innovation enables a firm to keep one step ahead of the competition by introducing a new series of products.
- seeking legal protection through patents, copyrights, trade secrets or trademarks.

While the global competition to discover cures for cancer is a highly publicised matter, in its shadows is a parallel segment of the industry that is equally active in the search for advances in methods for cancer screening and detection. For example, in the sub-disease space of cervical and skin cancers, traditional detection methods like the pap-smear have been in practice for decades and are largely manual and subjective.

Two key innovations are apparent. First, employing opto-electrical technology permits wider, instant data sampling, thereby reducing the probability of false negative results. Second, today's computing technology affords instantaneous multi-variable data comparison against a large standardised data source, which consequently minimises manual and subjective inaccuracies.

Polartechnics

Dr Malcom Coppleson and Dr Bevan Reid founded Polartechnics in 1987. As eminent professionals in the areas of clinical practice, gynaecology and biological research, they were qualified to question current cancer detection methods that were in practice (initially focused on cervical cancer). The founders' combined

their knowledge and experiences, which allowed them to challenge the effectiveness and efficiencies of existing methods.

The combined determination of Polartechnics' highly skilled team is manifested in the opto-electrical and algorithm technology platform that the company's current range of cancer detection products are based on. Polartechnics' efforts have been successfully rewarded through recognition of design excellence in Australia and the United States, as well as achieving regulatory approval and marketing success internationally. Polartechnics is currently in the final stages of commercialising revolutionary inventions for the detection of pre-cancer and cancer.

Corporate and Business Strategy

Polartechnics' corporate vision is to:
Develop and commercialise medical instruments utilising the physical characteristics of human tissue as a means of diagnosing pre-cancer and cancer in all their possible forms, and in achieving this objective, to pursue the highest standards of technology and professionalism.

This is a broad vision that highlight's Polartechnics orientation towards scientific exploration and investigation, which demonstrates the company's motivation to challenge current methods and techniques.

Polartechnics is a company whose core business is based on its technological competency to generate intellectual property that fulfills the company's corporate vision. The company's competitive advantage is considered to be its intellectual capital, which includes intellectual property such as patents, trademarks, as well as its unique reference database. The company is aware that international commercial success depends on partnering and collaborating with individuals and groups that have strong complementary competencies, such as key opinion leaders, to assist in winning market acceptance and reputable marketing partners.

Corporate Structure

Polartechnics Limited was floated on the Australian Stock Exchange in 1987 (ASX: PLT). The primary offices for Polartechnics are situated in William Street, Woolloomooloo (East Sydney) where the majority of the company's activities are located, including the intellectual property management and the coordination of clinical studies and trials. The company is currently in transition from a focus on R&D to manufacturing. Interim manufacturing space is being leased in Allambie Heights from a company licensed to manufacture sterile and non-sterile therapeutic goods for human use. Concurrently, Polartechnics is preparing its own in-house manufacturing facilities to be co-located with existing operations at the William Street site. Sales and Marketing are global functions shared through a number of partnerships with other companies with well-established marketing and distribution competencies.

Workforce and Culture

Polartechnics has a highly qualified workforce of over fifty employees. The composition of the workforce includes specialists in the fields of mechanical and electrical engineering, physics, mathematics, statistics, biomedical sciences and medicine. Whilst most of Polartechnics' workforce is based at the company's Sydney premises, there are a number of individuals based offsite. They are involved in activities such as clinical trials, marketing and manufacturing, some of which are spread globally in the key product markets.

The workforce at Polartechnics is organised around teams, as described by the company's Principal Scientist:

> "There are lots of teams of highly skilled people, for example we have clinician expert groups who choose this type of work; setting up and conducting clinical trials."

In-house capabilities are augmented through the sponsorship of experts in fields of scientific research that are relevant to Polartechnics' business. The principal scientist explained that as the product development cycle moves into the

production stage, Polartechnics took the strategic decision to reorganise much of its workforce into new manufacturing and marketing functions. An organisational transition of this type was achievable because of the flexible and multi-disciplinary nature of the people at Polartechnics. The principal scientist also stated that:

> "We have varying numbers of clinicians, with training in medicine. Qualified doctors who prefer to do this type of work [conducting clinical trials] rather than doing patient work. Some of them are moving across from that role into marketing."

Although retired, the founders' association with the company continues through their involvement with the company's Scientific Advisory Board. The legacy of the founder's (?) scientific approach to innovation are well entrenched in the corporate culture, and is still evident today.

The company's board and executives are driven by the knowledge that their cancer detection products are innovations that are capable of bringing vast benefits to its intended end-users, and, hence, disrupting the current basis of competition in the marketplace.

Commercialisation of Products

Polartechnics' core activities are concerned with the commercialisation of their products. Activities are broad ranging, and encompass many aspects of new product development (NPD), from idea inception, R&D, to manufacturing and marketing.

As noted above, Polartechnics is a company that has successfully developed commercial innovations for use in the detection of healthy, pre-cancer and cancer conditions. Their product offering comprises three core products as listed on the Polartechnics web site www.polartechnics.com.au/

Truscreen

Early detection remains the key to minimising the danger of developing cervical cancer, but improvements in test accuracy are crucial. TruScreen is a new approach that can help save lives. TruScreen provides immediate results and promises remarkable accuracy. It offers a procedure that can be performed entirely, in the physician's office.

The Company is working closely with its newly appointed Italian distributor, Deka, on developing the market in Italy for TruScreen. In addition, the marketing staff are following up the successful tender in Ireland for the supply of MediScan instruments to the value of over $500,000. The following activities are currently under way:

- settle end-selling price to doctors of TruScreen in Italy and the price of the product to Deka;
- publication of TruScreen clinical data in the International Journal of Gynaecological Oncology (published in USA) – the company's first major peer-reviewed scientific publication, which is in press;
- marketing program in Italy to progress beyond early technology adopters to wider customer base.

SolarScan.

The SolarScan system captures, stores and retrieves skin images. Its high quality image and advanced image analysis software assist the physician in diagnosing skin disorders. The powerful new SolarScan system provides a broad range of features for health professionals concerned with skin conditions. A key feature is the system's ability to assist the physician in detecting melanoma. Melanoma has one of the fastest growing cancer incidence rates in the world. In Australia, it is the third most common cancer in both men and women. Early detection is the key to reducing mortality and saving treatment costs. SolarScan offers unique benefits to physicians diagnosing pigmented skin lesions. It will enable:

- powerful real-time computer assisted diagnosis (CAD);

- high quality magnified skin images for immediate assessment by the physician;
- monitoring of lesions for short term changes (a strong indicator of possible melanoma);
- reduction in the number of unnecessary excisions

The following activities are currently under way.

- completion of a network version of SolarScan (capable of linking up several clinics in a group) and commencement of sales of that product;
- appointment of distributor and initiation of sales in the USA;
- attendance at a dermatological conference in Chicago.

MediScan.

MediScan is an advanced image, video and patient data management system. It is designed to capture, organize and distribute high quality images and digital video data with a minimum of effort. The MediScan system can be connected to flexible fiberscopes and rigid endoscopes, microscopes and macro cameras. Many medical procedures can benefit from the system through its high-resolution optical image capability such as:

- arthroscopy
- gastroenteroscopy
- colonoscopy
- rectoscopy

Polartechnics is currently pursuing the following activities in relation to the MediScan product:

- completion of customized product development for Olympus alliance and Olympus sales in Australia;
- appointment of distributors and initiation of sales in Europe;
- Federal Drug Agency (FDA) listing of the product for sale in USA

Polartechnics' core competencies lie in the specialisms necessary in developing biophysical technology platforms that use opto-electrical measurements of biological tissue and mathematical algorithms for comparative data analysis. Like Solarscan, which was a spin-off application of the TruScreen technology, these competencies provide the company with the capacity to explore a number of additional applications, with the appropriate architectural modifications for different types of tissue measurement sampling. Furthermore, Polartechnics' analysis algorithm can be reused in applications of varied contexts, even outside of the realm of biomedical sciences, adding additional scope for standalone out-licensing opportunities.

Intellectual Property Strategy

Polartechnics defines intellectual property as property that is not tangible, but which originates through the creative effort of the inventor. This is accomplished by encouraging innovation through giving the inventor the right of exclusive commercial use, and by encouraging competitors to design around the invention.

From the standpoint of the inventor, the purpose in trying to obtain a utility patent is to secure the exclusive right to make, use and sell the patented invention. Those exclusive rights exist for the term of the patent, as long as the renewal fees, which are required to keep the patent alive, are paid. If the invention is patentable in terms of subject matter, it must meet three statutory requirements: utility (usefulness), novelty and non-obviousness.

Intellectual property is considered to be one of Polartechnics' core assets. It is defined in the legal sense of patents, trademarks, registered designs, and circuit layouts. The company's collections of reference data are also considered to be part of its intellectual property. The Principal Scientist believes that the company's cervix and melanoma databases are the biggest in the world, attributing this asset to the company's network with numerous global clinical and research sites. Additionally, the company believes that the accumulated know-

how and experiences of its people are vital assets to the company. The value of tacit knowledge is comparable to all Balance Sheet assets combined. According to the principal scientist:

> "We have a number of extraordinarily valuable people, the loss of whom would be worth millions."

Alignment of IP with Business Strategy

Recently, the Business Review Weekly, Australia's most reliable business publication, identified intellectual property as one of the key secrets behind Australia's 100 top businesses. When people think of IP, they think of protection through patents, trademarks and copyright. However, the real value of IP is the way in which firms can use it as an integral part of their business strategies – marketing, capital raising, research and development or business development.

Over the last decade, Polartechnics' business strategy has evolved as the company has continued to actively realign its corporate objectives with emergent commercial opportunities. A pertinent example is the redesign of the TruScreen product to incorporate a proprietary Single Use Sensor (SUS). The SUS is a disposable element that was not anticipated in original designs. It is the innovative outcome that solved the challenge of sterilising a reusable probe. Although it was an adjunct product to the main TruScreen product, the SUS provides the company with a significant revenue stream.

Intellectual property in the form of patents is considered to be an essential part of the company's business strategy. From a corporate standpoint, patents signal the promise of exclusive rights to commercial returns. During the product prototyping stages, when the company's revenue stream was insignificant, legal claims to these intangible assets were important milestones to attract support from financing and marketing partners. This is reflected in the principal scientists' comment below:

> "Without which, nothing is worthwhile. Without patents it is not possible to attract funding, or to be profitable."

The key lessons learned in developing an intellectual property strategy at Polartechnics are:

- search the patent and trademark databases and other literature to ensure that the firm's ideas are new and also to avoid infringing the rights of others;
- maintain secrecy and aim to be the first to market;
- develop an infringement strategy;
- educate the staff as to their obligations and have staff sign confidentiality agreements where necessary;
- be confident about whether or not the firm actually owns the IP it thinks it does;
- consider ways that the firm can use the intellectual property system in their overall business strategy;
- make effective trademarks the core of the firm's brand and image building strategy;
- identify and value the firm's IP assets and ensure they are itemised in the business plan.

Protection and Management

Currently Polartechnics has developed two products that are based on the company's opto-electrical technology platform. The principal scientists stated that:

> "Only half of them [patents] are embodied in the current product. The others are there because they are potential variants on the way we make the product. For example, a group of patents describe a hybrid arrangement of components, thus providing options for future applications."

Networks and Collaborations

Polartechnics has an extensive network of collaborators and partners at various stages of product development. During the intensive R&D stage, Polartechnics worked closely with the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The CSIRO provided valuable contributions to the development of the core algorithm used by both the TruScreen and SolarScan products. Similarly, input into the development process by the University of Sydney Melanoma and Skin Cancer Research Institute (MASCRI) was not only critical to the development of the SolarScan product, but also continues to add value to the product. This collaboration is now of strategic marketing importance as the SolarScan product is able to leverage on its association with MASCRI though the Institute's endorsement on product marketing materials. The principal scientists elaborated on the key issues:

> "Difficult to find people with the competence, as it's a complex and multi-disciplinary device and when I start talking to university people they glaze over after a while because I invariably drift into an area that is outside their competence."

Polartechnics has, for more than a decade, been devoted to research and development. The primary driver has been a mission to transform a theoretical concept into a commercial product. Private funding from varied sources and government grants were fundamental to the early beginnings of the company's R&D activities. Once product prototypes showed commercial promise, Polartechnics' intellectual property won the confidence of prospective marketing partner Ethicon. An agreement was struck, which included upfront funding, and later, financing contributions to clinical trials. The company's strong focus around the vision of end products has influenced Polartechnics' activities and organisational structure. Today, Polartechnics' commercial offering comprises three commercial products, each of which have achieved milestone acceptance by national regulatory bodies.

Innovativeness

Polartechnics has spent more than a decade in developing an opto-electrical technology platform and the complementary algorithms. These innovations have been primarily concentrated on building applications for cervical cancer detection. In the last three years design and approval of a successful commercial device was achieved. The SolarScan and MediScan products quickly followed, the former being an application variant to the TruScreen product. The TruScreen product itself went through several major modifications prior to its current completed state. Polartechnics senior management learned several lessons during this process. For example, without involving key opinion leaders in the development process, Polartechnics would not have been able to deliver a product that meets the markets' requirements.

Polartechnics also realized that early licensing of intellectual property rights has a number of benefits including reaching a larger market, exploiting further applications, establishing standards, gaining access to complementary technology, blocking competitive developments and converting competitors into defenders.

Market research through networking within the medical industry played a key role in enabling Polartechnics to assess the possibilities for future product applications that can exploit the company's intellectual property assets.

In 2001, two Australian Design Awards recognised Polartechnics' innovative achievements in the areas of Software and Electronics Design and Engineering Design. This is further evidence of the innovative culture that is characteristic of Polatechnics.

Enabling Business Practices – Systems and Information Technology

Quality Assurance Services (QAS), Standards Australia, recently audited Polartechnics. This has resulted in Polartechnics being registered for compliance to the international quality standard ISO 9001. The registration covers the

Company's quality management system for the design and development of medical devices for cervical cancer detection. The following comments from the principal scientist are indicative of Polartechnics approach to quality and data management:

> "The quality control section is only one person who is specifically designated to that team, [however] quality permeates everything. Everything is done according to approved practices."
>
> "Data are critical assets for Polartechnics. The company is very serious about the protection of its data and designs."
>
> "Because much of the value of our company is in our database we can't afford to risk anyone hacking in, therefore we have 50-60 internal computers [single site] are linked to our intranet and most of our communications is facilitated through that [internally]."
>
> "Communications that are put out over some other medium like Floppy or CD and checked for viruses are only then allowed to be put into our intranet."
>
> "We have someone who vets all the incoming email, the junk mail items get filtered out, and then the other mail is distributed to us individually."
>
> "Everything, all our plans, our specifications, inventory control, ordering are all computer based."

Polartechnics prefers to innovatively acquire access to necessary complementary assets to achieve commercial reality. Management believes that time to market is crucial in achieving successful commercialisation.

Culture is a key element of Polartechnics success. The culture is responsive to emergent changes to the environment, and is able to realign deliberate strategies to ensure that progress is made in the direction of achieving commercial success. The company encourages innovation, optimism and perseverance. This is most observable in the company's ability to action significant architectural changes to the original innovation concept when it comes to new product development.

Polartechnics is a good example of an SME that successfully applies strategic patenting to achieve competitive advantages without expending too many of their

own resources. Polartechnics concludes that the first prerequisite of strategic patenting is the active observation of competitors' patenting portfolios, which is necessary to identify market niches and to place products in the right position in the market.

Implications for Managers

Intellectual property is a key factor of competitive advantage for biotechnology companies. An important implication for managers is that the protection of intellectual property alone through legal regimes like patents, cannot alone lead to successful commercialisation. Investment into legal claims over intellectual property needs to be considered in the context of the firm's business strategy and business risk. Other methods of protecting intellectual property, like secrecy and management of know-how represent effective forms of protection not to be overlooked and they are equally deserving of management and capital commitment.

A further implication for managers is that the patent system should encourage innovators to share their discoveries with the general public and hence advance the general status of technology. This advancement is accomplished by encouraging innovation through giving the inventor the right of exclusive commercial use, and by encouraging competitors to design around the invention.

Applied Biosystems[2]

Abstract

The case study is based on the Australian arm of the multinational company Applied Biosystems. Applied Biosystems is a global biotechnology company with its main office in the United States. The company's core business is to develop and commercialise instruments and reagents for the automated synthesis and analysis of biomolecules.

A case study protocol was designed to gather the qualitative data by conducting face-to-face interviews with the company's Managing Director and Product Development Manager. The case study identifies and explains how best practice in intellectual property is implemented for successfully commercialising product innovation. The case study explores Applied Biosystem's strategic view and practices around intellectual property by highlighting the strengths and challenges faced by the company in this area in its pursuit of commercial success.

Intellectual Property in the Australian Biotechnology Industry

The biotechnology industry is considered to be a high-tech knowledge intensive industry. The industry's main objective is to develop new products founded on new ideas. With the creation of new ideas comes the need to protect one's intellectual property. While securing a patent is one possible central strategy for managing intellectual property, there is substantially more involved in managing intellectual property effectively. Breakthroughs in life sciences today are achieved with the

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[2] This case was written by Dr Mile Terziovski and Amy Lai, EACC, University of Melbourne

assistance of a breed of sophisticated tools and techniques for data collection, processing and analysis. Examples of tools that lead the way include instruments used in DNA sequencing, Polymerize Chain Reaction (PCR) and mass spectrometry. These tools are coupled with advancements in chemistry knowledge – biochemicals and reagents – all of which have radically changed the way research is conducted.

When a research program is initiated, enthusiasm and high ideals may lend to overlooking the need to think about the outcomes of the program. First, one needs to determine who is researching in a similar area and what patent rights already exist. A research team does not want to make a substantial investment in a program that violates another's intellectual property rights. Next, to ensure that the program leads to fruitful outcomes, an intellectual property strategy should be developed. It is essential for a company to develop a web of patents that will be commercially successful, rather than to have a fragmented set of non-related property. That is, there is synergistic value in developing an interwoven web of patents to deter competitors in your target area.

Applied BioSystems

Applied Biosystems was first established in Australia in the mid 1980's. Since then, Australia has grown into a regional business, from an agency with 2 staff to a fully owned subsidiary with more than 50 employees. Globally there are 4500 employees at Applied Biosystems. Although the activities of the Australian entity are focused around a core of marketing and after-sales support functions, the skills mix of the workforce is predominantly technical and scientific; with emphasis on the fields of biosciences and engineering (of which the majority is of electrical engineering). Additionally, a proportion of the workforce has attained higher degree qualifications, a number of which are PhDs.

Applied Biosystems was established based on a vision that there was a problem to be solved. At that time, the problem that was recognised by its founders, who included technologists and venture capitalists, was that there were obvious deficiencies in the efficiency of the current research processes. Researchers yearned for better ways to enable them to do their research. Thus, the inspiration for a "tool company" that

could create advanced research instruments was conceived. The company Applied Biosystems was formed in 1981 with a mission to exploit the identified market opportunity in the life sciences sector.

Applied Biosystems' first year was filled with rapid growth and milestone accomplishments. The company successfully established a reputation for its innovation and commercialization competencies. By 1982 the company had grown to a base of forty employees, released its first commercial product and reported US$402,000 in revenues. In 1990 Applied Biosystems was floated publicly on the NASDAQ. Further growth ensued through the broadening of the company's global strategy including establishment of subsidiary operations in marketing and manufacturing.

Applied Biosystem was also intimately aware that by supplementing its own in-house capabilities it would strengthen the company's opportunities for commercial success. The company continues to proactively seek acquisitions and strategic collaborations with established entities to gain access to complementary assets such as established marketing distribution channels and manufacturing capabilities.

Notable organizational change came in 1993 when Applied Biosystems merged with the bioscience giant Perkin-Elmer; with whom the company previously had joint marketing agreements. The premise of the merger was to capitalize on the emergent industry trend of rapid growth in the life science market. It was a synergistic merger that would provide exceptional benefits to both companies. Subsequent to the merger the company was renamed PR Biosystems, but reverted back to the name Applied Biosystems in 2000.

Today the company remains as an operating group of the Applera Corporation (formally the Perkin Elmer Corporation). Applied Biosystems continues to be a global leader in the development, manufacturing and marketing of instruments and reagents for the automated synthesis and analysis of biomolecules (DNA, RNA and proteins).

Corporate and Business Strategy

Applied Biosystems remains committed to being a "tool company" that delivers value to its customers in the enormously progressive life sciences marketplace. Its founding mission more than twenty years ago was stated as:

> *"To develop, manufacture and market biochemicals and automated instruments for biotechnology research and diagnostic applications."*

For a new startup company this would seem to be a bold objective. However, the company's historical success would suggest that a strong Business Strategy complemented by skilled execution facilitated Applied Biosystems accomplishment of this mission.

Today the company markets more than twenty-five instruments and four hundred biochemical products globally. Published strategy statements essentially remain unchanged. Applied Biosystems' Corporate strategy is summarized in the following statement:

> *"Applied Biosystems has demonstrated its position as a technology leader and driving force in the changing dynamics of the life science marketplace. The Applied Biosystems business is focused on the following markets: basic research, commercial research (pharmaceutical and biotechnology) and standardised testing, including forensic human identification, HIV genotyping and food testing. The company has an installed base of more than 50,000 instrument systems in approximately 100 countries".*

Applied BioSystems' business strategy is summarized in the following statement:

> *"Basic research includes work at university, government and other non-profit institutions that focus on uncovering the basic laws of nature. This business represents about half of the revenue of Applied Biosystems. An additional one-third of the revenue of Applied Biosystems is from pharmaceutical and biotechnology companies that are applying the company's products to molecular medicine: discovering new drugs more effectively. The remaining revenues come from standardised tests for customers who place priority on precise results from a high volume of automated tests."*

Corporate Structure

Applied Biosystems is one of three subsidiaries of the Applera Corporation; the other two subsidiaries are Celera Genomics and Celera Diagnostics. Applied Biosystems has its corporate head office in California, United States. Research and Development is centralised there, along with the company's corporate research initiative called the Scientific and Technology Exploratory Group. Similarly, global management of intellectual property matters is centralised at the company's main offices.

Manufacturing, Distribution and Marketing are functions located in numerous offshore locations with proximity to major markets. The Australian arm of Applied Biosystems is primarily a Marketing and Distribution subsidiary servicing the Australian and New Zealand markets. It is concerned with Sales and Service and Technical Support activities. The Australian subsidiary is also active in providing market feedback contributions to the corporate group.

Workforce and Culture

Innovation is very much a part of the corporate culture at Applied Biosystems. At a global level, Applied Biosystem maintains its reputation as a market leader with a continuous flow of new product innovation. The company's new product development processes are structured and controlled to effectively manage the outcomes from creative efforts. The company fosters a culture of creative freedom, yet it has a commercialization competency to transform ideas into marketable products. At a regional level, this culture of innovation is disseminated across the company's multiple sites and carried through all of its business functions. Applied Biosystems Australia can be described as taking an innovative approach to its local operations. A statement by the company's Logistics Manager demonstrates an example of innovation being infused into its corporate culture:

"Innovation Management is part of our DNA"

The Australian subsidiary is proactive in a number of areas including continuous improvement of organizational practices and processes, customer relationships and promotion of the company's competencies. These efforts contribute to strengthening Applied Biosystem's leadership position both locally and globally.

Core Activities, Products and Services

Applied Biosystems derives revenue through a diversity of product and service offerings. The company develops and markets instrument-based systems, reagents, software and contract services to the life science industry and research community. The company's core revenue streams are based on sales of its three primary product lines:

- DNA sequencing instruments and reagents.
- Sequence Detection Systems instruments and reagents for performing real-time PCR (polymerase chain reaction) and other genomic products.
- Mass spectrometry-based systems

Almost half of the company's revenues are generated through sales of instruments, including software products. More than one third or revenues are achieved through the sales of consumables (reagents and disposables), and a remaining portion of sales are derived through other offerings such as service contracts on instruments, royalties, license fees and contract research. Functions performed include systems configuration, customised programming, and project implementation.

Applied Biosystem's business model is geared towards providing added-value for its clients; combining a number of its offerings that may cover product supply and software customization or full turnkey project implementation. The company holds a leading market position where, in many cases, customers eagerly offer to participate in early access programs in the belief that they will, themselves, gain an opportunity to achieve competitive advantage.

Applied Biosystems products can be classed into three main high-level categories: 1. Instrumentation 2. Reagents and 3. Software. Of the three, the nature of software development and methods to protect proprietary knowledge in software implies

greater difficulty for imitation than mechanically orientated instrumentation. Chemical reagents are also more difficult to reengineer that mechanically orientated instruments. As software is an integral component of much of the instrumentation and turnkey solutions, Applied Biosystems is faced with the challenges surrounding lack of international convergence and still largely immature legal protection frameworks.

Intellectual Property Strategy

Strategic Point of View

> *"Many companies are first set up on a technology and then look for problems to solve. Applied Biosystems was different."*

This quote from the director of Business Development illustrates how Applied Biosystems was founded on an approach that innovation should be developed after a value proposition has been defined. In order to find the "problems to solve" the company is placing this responsibility on its people.

Intellectual property is considered to be multi-disciplinary phenomena as stated by the Managing Director below:
"Creating a strong intellectual property position is cross-functional and requires commercial, technical, and legal contributions and support."

Alignment with Business Strategy

The rapidly evolving nature of the life sciences marketplace places pressure on tool companies to be able to satisfy the changing needs and requirements of its customers. Applied Biosystems' ability to predict and respond quickly to changes, sometimes not yet perceived by the mainstream, is a source of competitive advantage. The Australian Managing Director describes this achievement as being attributable to effective navigation through:

> *"Clear input from businesses and "gurus" regarding the truly important problems to be solved. [Through] owning the responsibility to identify and*

acquire intellectual property, …knowing the technical literature and patent landscape, [and]…establishing relationships with "thought leaders" in key technical disciplines."

Overall, the influence of the company's position in the marketplace has yielded in motivating the direction of market trends. Applied Biosystem's closeness with leading users underlies the opportunities for the conceptualisation and delivery of new technology platforms and products ahead of competitors in the field. Consequently, intellectual property generation is a continuous and major activity that is linked closely with the company's business strategy.

Whilst Applied Biosystems' clearly maintains that intellectual property is a core part of its corporate identity, it is observable that business drivers also provide a critical balance to navigating commercial realities. For example, late-stage new product development projects will be halted if confidence in an emergent market demand cannot be identified.

Protection and Management of Intellectual Property

Applied Biosystems employs a number of methods to protect and manage intellectual property. The company has established formal strategies and structure around the management of its extensive intellectual property portfolio composed largely of patents, trademarks and copyrights. The main R&D base and the intellectual property management function are centralized in the United States. A dedicated team in excess of thirty staff represents this department with support from consulting specialists, predominantly in a legal capacity. This combination of multi-disciplinary professionals is responsible for the management of intellectual property matters internationally.

However, there is a strong belief that even protection under legal regimes such as patents, Applied Biosystems cannot provide a foolproof defense from imitators. The following statement from the Product Development Manager reinforces the relevance of defence in many organizations.

"Patent protection is only effective if the patent can be successfully defended."

Defence is termed not only in the legal reactive sense of litigation against infringement, but in a broader view that encompasses a continuous strategy and practice; beginning prior to the filing of a patent and extending beyond the term of a patent's prescribed lifespan.

The impact of this strategic approach is translated through to the company's business performance. Over the last three to five years, the sources of revenue at Applied Biosystems have increased considerably. In particular, revenue derived through non-product sales – royalties, licensing and contract research continue to grow. In the first quarter of 2003 this formed 17.3% of total revenue, up from 15.0% in the same quarter of the pervious year. The performance of these types of revenue streams indicates that intangible assets like knowledge and know-how continue to be increasingly significant.

The key to the success of this strategy is a culture where innovation is considered to be a shared value and, as such, Applied Biosystems places high priority in developing and maintaining its people, as reflected in the statement made by the Managing Director below:

> *"People are our greatest asset. Our ability, flexibility and motivation underpin all of our financial results, customer satisfaction and operational activities. This relies heavily on our ability to innovate, learn and improve at an individual level, which collectively delivers the result for the whole organisation."*

The culture fosters a capability to protect intellectual property informally through maintaining trade secrets. This is coupled with the ability to control information and knowledge flows both internally and with external collaborators. These strategies are effective in strengthening Applied Biosystems' distinctive technological competencies and intellectual property base.

Networks and Collaborations

Networks and collaborations are an important part of Applied Biosystems' strategy. The company maintains diverse upstream and downstream collaborations, in a network that includes both public and private groups. Historically, external collaborations have always contributed to internal processes. The company's commitment to corporate research is seen in the establishment of the S&T group, which continues to operate on a mandated "outward focus on customer needs". This is reflected in the following comment made by the Managing Director:

> *"We continue to look to our customers as a source of new ideas to give us a broader perspective on the market and to maintain close ties with universities to keep us focused on the researcher's needs."*

Applied Biosystems is proactive in seeking customer feedback by using methods such as customer satisfaction surveys. The objective is to ascertain customer perceptions of their "innovative solutions" needs. This approach is reflected in the comments below made by the Managing Director throughout the interview process:

- *"Anticipating market needs by developing the right products at the right time"*
- *"Be the leaders in technological innovation"*
- *"Provide integrated products and services"*

Applied Biosystems have also established strategic partnerships with their customers. For example they have a direct customer relationship with Celera Genomics, also a subsidiary of Applera Corporate, Celera is a leader in delivering genomic content to the global marketplace. This collaboration plays an important role to reinforce the value of the technology developed by Applied Biosystems.

The company continues to maintain control over intellectual property by balancing internal manufacturing and a business driver of minimizing lead-time to market. Where external complementary assets are identified, Applied Biosystems proactively establishes alliance partnerships. Collaborations continue with international best-practice companies like 3M high volume manufacturing and Hitachi's rapid prototype turnaround.

Intellectual Property Practice

A centralised intellectual property management team of highly qualified people is responsible for all matters related to intellectual property, from the coordination of patent and trademark registration in all key global markets through to managing infringements and other strategies for defence. This team provides a vital link between technology and commercial reality. By working closely with corporate researchers and specialized legal consultants, the intellectual property management team aim to ensure that Applied Biosystems is prepared to defend its intellectual property rights. For example, in the Financial Year 2002, Applied Biosystems challenged two major cases of patent infringement.

The corporate policy for managing external issues related to intellectual property is to maintain a centralized spokesperson from the corporate team in the United States. Employees in Australia are not permitted to become involved in intellectual property related issues. Should the need arise, legal disputes are resolved by the centralized corporate intellectual property team based in the United States. As Australian activities are largely face-to-face with customers, this may, at times, be a difficult situation. However, it is a policy that helps to safeguard intellectual property by keeping it centralised.

Innovativeness

Applied Biosystems continues to be a highly innovative organization. The company believes that they have made crucial contributions to two major advances in the industry:

- introducing genome segmenting;
- making genome segmenting less expensive.

In the past three years the company has introduced many new products and services, in particular, with respect to the research tools and instrumentation range. Incremental continuous innovation has been the main strategy in developing new products incorporating the latest advances in computer hardware and software technologies. However, the primary driver is still the evolving demands of lead users who include world-class public and private research groups. These customers are integral to the process of generating new intellectual property. The new business offering called

"Knowledge Business" represents an example that combines changes in market and technological limits. This concept is reflected in the statement made by the Managing Director:

> *"Knowledge Business is a logical evolution. …With the Knowledge Business, we have come full circle: providing an information and product portal that enables researchers focused on smaller-scale biology projects to take full advantage of the knowledge emerging from industrial-scale, high-throughput biology programs. …we also envision that the Knowledge Business will provide an opportunity to build on our already substantial genetic analysis business."*

Applied Biosystems has a performance target that measures revenue contributions attributable to new products. This is both a top down strategy as well a response to customers who continually make enquiries about Applied Biosystems' new products. This strategy is similar to that of the reputable 3M organisation. In a recent customer satisfaction survey 80% of respondents answered the question *"Why do you keep coming back?"* with an answer *"Due to innovative new products."*.

Organisation learning is further attributable to this customer-centric focus. As an industry leader, learning to anticipate market needs and achieving rapid lead-time to market is considered to be an effective method for the company to accelerate their product development process. Applied Biosystems also works closely with external consultants to navigate the external environment, including the patent landscape.

Implementation of Protection and Management

Innovation Management is a core agenda item for Applied Biosystems. The company's perspective on innovation management highlights two key areas of importance according to the Managing Director:

- *"Create an organizational culture that values innovation."*
- *"Competitive advantage and intellectual property."*

Applied Biosystems proactively surveys the competitive environment and intellectual property landscape. The aim of this practice is to discover ways to minimise the costs and expenses associated with a threat to the company's competitive advantage. There have been a number of cases won in intellectual property litigation. For example, in March 2002, in a process that lasted more than 2 years, Applied Biosystems' defended a legal claim and recovered USD52.6million.

All employees are engaged in the innovation process. This is formally measured via an Employee Competency Assessment where rewards are tied to innovativeness at all levels and functions within the organization.

Applied Biosystems is structured along the lines of cross-functional project teams. These teams have demonstrated benefit to increasing effective commercialization lead-times. Applied Biosystems espouses a culture that supports fast failure. For example, when indications of any new product development objectives cannot seem to satisfy technological or market requirements the project is cut-short and abandoned as early as possible so that unnecessary resources are not spent on an unsuccessful product.

Enabling Business Practices – Systems and Information Technology

Applied Biosystems is a multi-national corporation with activities ranging from research and development through to manufacturing and marketing. However, the nature of the marketplace in DNA research is such that issues and needs of customers are globally relevant. By centralizing systems for strategic, R&D and administrative functions Applied Biosystems can effectively manage modifications of products for regional appropriateness that supports localized regional manufacturing and marketing. This is particularly observable in the Applied Biosystems' Australian operation that can articulate corporate strategies and practices seamlessly.

The Australian Managing Director conveys a unified statement regarding elements of the company's strong intellectual property strategy:

- *"Freedom to operate: we are not blocked or penalized by other people's*

intellectual property."

- *"Protected products: our products are protected by a strong Applied Biosystems intellectual property position that ensures ongoing technological exclusivity."*

As a globally marketing biotechnology company, Applied Biosystems manufactures and manages collaborations with external manufacturers who are compliant with ISO 9001. The quality system assures the maintenance of consistent quality irrespective of the manufacturer. Additionally, benchmarking within and external to the industry is also a practice prevalent within the company.

Other internal initiatives such as practices directed to employee satisfaction are also critical systems that protect the company's intellectual property from employee "brain-drain". A real threat to competitive advantage occurs when skilled individuals disclose tacit knowledge to competitors. Programs such as encouraging new idea creation through "New Idea" days and "Star Award" recognize and rewards innovation.

Computer-based technologies are recognised to be an essential part of Applied Biosystems' operation. Deployment of information technologies across multiple sites and geographies serves to enhance effective coordination and communications. The company's portal initiative enables multi-functional groups self-service access to a centralized source of information from Human Resources functions through to global knowledge bases.

Additionally, internet-based applications are integrated into the company's operations. Supply chain B2B integration and extended channel sales strategies through direct e-commerce and participation in electronic marketplaces provide effective process enhancements.

Conclusion

Applied Biosystems is a leading global company with global networks internally and externally. The company focuses on maintaining differentiation through its

intellectual property strategies in order to sustain competitive advantage and market leadership.

This is being achieved through the deployment of R&D efforts in the form of registered patents. The company has a strategic view that licensing of intellectual property to competitors will allow the company's proprietary innovations to become the de facto standard.

Applied Biosystems is able to predict and anticipate new trends by working closely with lead users and motivating their customers to achieve competitive advantages. This is a shared vision with customers who are loyal in their long-term relationship with Applied Biosystems that is based on a promise of being an early adopter of new technology.

The underpinning concept in the company culture is innovation. This is largely attributed to strong leadership that has communicated the importance of innovation across the company. While operations in Australia are limited to sales and after-sales functions, the group actively contributes to global efforts of commercialising intellectual property.

Implications for Managers

Managers must lead and foster a culture that extends to its entire workforce. Motivating people to appreciate intellectual property issues is critical. In an organization whose activities are based around high-rates of intellectual property generation, appropriate systems and measures are an imperative in order to avoid undue loss of knowledge and know-how.

Legal regimes can provide satisfactory results, but a cost-benefit evaluation will not always arrive at a conclusion to pursue defensive action. The underlying requirement is clearly articulated in the statement:

> *"Patent protection is only effective if the patent can be successfully defended."*

Effective legal protection over intellectual property should be planned and the company should have a strategy in place and be prepared for the occasional dispute. Trademarks and copyrights are equally important to ensure that new geographic

markets have a common understanding of what the company stands for, in service and in product delivery and performance.

Managers of new technology, research and development should consider objectively, emergent trends in cross-functional areas, in addition to contributions from the marketing group. These trends may be applicable and relevant, and offer new methods that can capture and predict future market needs. This includes practices like concurrent designing-in of technological advances in computing capabilities. Such outcomes build on a technology platform, which offers product differentiation and business value as integrated technologies evolve.

Starpharma Limited[3]

Abstract

This case study highlights best practice in intellectual property strategy and practice for the successful commercialisation of innovation at Starpharma. A case study protocol was developed and used in a face-to-face interview with the company's Intellectual Property Manager. Starpharma is an Australian biotechnology company whose core business is to develop and commercialise new pharmaceutical drugs based on innovation in the emerging field of dendrimer science. The case study explores Starpharma's strategic view and practices around intellectual property by highlighting the strengths and challenges faced by the company in this area, in its pursuit of commercial success.

Innovation and Commercialisation Success

When a firm releases new innovation into the public domain there is a risk that it will be imitated and reproduced. In such situations, hard earned competitive advantage is severely diminished in a shorter time than it took to accumulate. This kind of risk significantly reduces the incentives for innovation, when the innovator cannot ensure some form of protection and "first-rights" of taking an idea to market.

In business terms intellectual property is commonly regarded as being linked to a firm's competitive advantage. Corporations that are able to sustain competitive advantages and enjoy commercial success know that there is a necessary mix of legal and non-legal mechanisms combined, that are required to minimise the risk of losing ownership and control of their creations and commercialisation opportunities.

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[3] *This case was written by Dr Mile Terziovski and Amy Lai, EACC, University of Melbourne*

Biotechnology in Australia

Advances made in the broad field of biotechnology are increasing at vastly rapid rates and the associated intellectual property presents significant opportunities for commercial exploitation.

The science of dendrimers is relatively new; the discovery was made in 1979 by a team led by Donald Tomalia at Dow Chemical Company (USA). It was not until 1992 that Dendrimers were available commercially, produced by Dendritech, Inc., a company founded by the same dendrimer pioneer, Donald Tomalia. Today Donald Tomalia has partnered with Starpharma to jointly establish the company Dendritic Nanotechnologies Limited (DNT), managing 33 key patent families, involving over 182 granted patents worldwide in the dendrimer science space.

In the field of pharmaceutical drug development, the growing momentum and advancements in research and development of dendrimer technology are offering increasingly optimistic possibilities for global commercial applications. In the last ten years alone, the number of publications and patents in the global field has risen ten-fold to more than 1500 in 2001. In particular, the pharmaceutical industry has recognised the possibility that applications of dendrimer-based nanodrugs will be capable of filling a market void where the adequacy of traditional “small” drugs has been deficient.

Protection of intellectual property is at the core of the business for biotechnology firms. According to a recent study, intellectual property protection is the second most important external factor, which influences companies’ decisions to invest in and use biotechnology. Companies were asked about the reasons for using and the extent to which they make use of patents as a means of protection for invention.
The main reasons to apply for patent protection are the safeguarding of the developed technology and its commercialisation, the competitive advantage and the provision of better negotiation positions for licensing agreements. Participants in the study also confirm that the patent system is important for biotechnology entities as an incentive system for research and development investments.

The degree of patenting depends very much on the degree of competition in the market. Large firms, more than small and medium sized firms, confirm that their patents are being used as a tool to defend one's technology. Biotechnology SMEs which are more restrained by their economic resources, also use strategic patenting to achieve competitive advantages without expending too many of their own resources. The first prerequisite of strategic patenting is the active observation of competitors' patenting portfolios, which is necessary to identify market niches and to place products in the right position in the market.

Starpharma

The Starpharma group is a research and development company that was established in 1996 to commercialise novel polyvalent compound technology discovered at the Bio molecular Research Institute (BRI), Melbourne, Australia. The BRI was formally part of the Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Starpharma is one of the early pioneers in the field of dendrimer science. Dendrimers have shown potential as drugs to prevent the spread and growth of secondary cancer (metastasis). Starpharma is developing drugs, called "angiogenesis inhibitors", which act by reducing the growth of new blood vessels to growing tumours therefore restricting tumour growth. Dendrimers have shown therapeutic potential in animal models of breast and colon metastasis. Further angiogenesis inhibition may also have application as a treatment for arthritis, retinitis and asthma. Angiogenesis inhibition is a new area of cancer research and there are currently no commercially available drugs in this area.

The company's establishment was motivated by the vision that there is significant commercial potential for real-world applications based on dendrimer technology. Today Starpharma continues to be a global player, committed to transforming dendrimer technology into commercial applications for the pharmaceutical market.

Corporate Structure and Business Strategy

The Starpharma Group ("Starpharma") is an Australian-owned Research and Development organisation consisting of three subsidiary companies operating under a parent funding entity established as a Pooled Development Fund (PDF). Starpharma Pooled Development Limited is a registered PDF and the primary funding entity for Starpharma.

Since its inception, Starpharma's structure has evolved to reflect the activities it will concentrate on as it develops its intellectual property and licensing opportunities. There are currently 3 wholly owned subsidiary companies in the Starpharma Group:

- Starpharma Limited, which holds the licence for the technology and manages the Group's intellectual property portfolio. Starpharma Limited also manages research programs, START grants and administrative functions for the Group.
- Viralstar Limited, which has agreed to provide research funding for further development of the technology in the field of antiviral therapeutics. Viralstar may become involved in the commercialisation process of this area of the technology.
- Angiostar Limited, which has agreed to provide research funding for further development of the technology in the field of inhibition of angiogenesis. Angiostar may become involved in the commercialisation process of this area of the technology.

Private investors who had a vision for the commercial potential of the technology initially funded Starpharma. The company raised further capital through a public floatation in September 2000, when the group was listed on the Australian Stock Exchange as Starpharma Pooled Development Limited (ASX: SPL). Today the group comprises three wholly owned subsidiary companies: Starpharma Limited, Viralstar Limited and Angiostar Limited, which owns 49.99% of DNT (incorporated in Delaware, USA).

Starpharma's CEO presentation to the 2002 AGM clearly highlights the foundations of their value proposition:

- *Dendrimers are a basic building block of nanotechnology*
- *Nanotechnology is the most exciting new technology of the 21st century*
- *Nanotechnology has the potential to transform industries by producing a whole range of new products*

The company's 2002 Annual Report further re-enforces their vision of exploiting their strong technological and commercial competencies:

- *"Developing high-value dendrimer nanodrugs to address unmet market needs".*
- *"Enabling the incorporation of dendrimer technology into new opportunities".*
- *"Enabling the use of dendrimer technology to enhance existing drug products".*

The translation of Starpharma's corporate strategy into the company's business strategy is well focused. Starpharma has a vision for developing and sustaining its core competency as a technological leader of an emerging base technology - dendrimer science - and adding-value through identifying and developing applications with commercial potential. Coupled with these objectives is a major emphasis on defining and establishing relationships with other groups who can provide the necessary complementary assets that are required to realise commercial success in delivering dendrimer-based pharmaceuticals to a worldwide market. Starpharma Limited is the group's operational entity concerned with the management of research programs, grants and administration. Viralstar Limited and Angiostar Limited are R&D entities specialising in the respective fields of antiviral therapeutics, and the inhibition of angiogenesis.

Workforce and Culture

The Starpharma group is a 'lean' organization comprising 22 employees, more than half of which are engaged in research and development (R&D) capacities. The workforce is highly educated, with 11 employees holding PhD qualifications. The

Senior Management Team, representing one third of the organisation, can be characterised as possessing a multi-disciplinary outlook and strong appreciation of technology, with almost all members holding at least one qualification in the field of science.

The small size of the workforce is conducive to fostering heightened awareness amongst all employees of the business and activities in which Starpharma is involved. Roles and responsibilities for individuals within the organization are broad and not limited to specific technical functions; this is a product of the culture at Starpharma. An example of the culture can be observed by the response of the Intellectual Property and Commercialization Manager upon discussing formal procedures for managing intellectual property, he indicated that:

"Intellectual Property is embedded in our culture"

DNT operates autonomously from Starpharma, with an independent organizational structure with 15 employees. In the initial stages of the investment relationship, Starpharma was an active collaborator, supporting the maturation of DNT's operational effectiveness and influencing the direction of its R&D activities.

Core Activities, Products and Services

The company focuses its pharmaceutical development efforts around the dendrimer platform technology (class of compounds). Starpharma's development objectives are differentiated from other industry players in which the company's dendrimer patents are based around the use of dendrimers as pharmaceuticals, rather than use as drug carrier molecules. At the core of this differentiation is the high value-added and significantly "complete" nature of its pharmaceutical products; positioning Starpharma for a strategically different relationship model with "Big Pharma" than is predominant with many other biotech companies.

One product example is the ViaGel, one of Starpharma's most advanced products from the company's core development focus area of the prevention of STDs. The ViaGel is a topical vaginal microbicide gel that is currently being prepared for submission as an Investigational New Drug (IND) to the FDA in the United States.

The cutting-edge nature of this area of drug development will see Starpharma being the first applicant to undertake human trials of a dendrimer nanodrug. Starpharma is accelerating the lengthy new product development (NPD) cycle of pharmaceutical development by marketing two early generation dendrimer products available through the international chemical supplier Sigma-Aldrich. These product offerings aim to establish an awareness of the Starpharma's capability to produce quality materials. In addition to a growing product range, Starpharma offers specialised dendrimer related analytical services (mass spec, NMR, CE, etc.). Their success in consulting and contract services draws attention to the industry's regard for Starpharma competency and expertise in the field of dendrimer science.

The investment in DNT, Inc. provides Starpharma with access to DNT's rich intellectual property portfolio, which currently consists of 33 patent families (182 issued patents), strengthens its position to consider new applications for nanodrug and accelerates the product development process. Currently, DNT markets approximately 12 dendrimer products through the Sigma-Aldrich catalogue.

Intellectual Property Strategy

Starpharma is a company that grew out of a need for a commercial vehicle to transform an existing set of patents into commercial reality. Since its establishment, Starpharma has developed and acquired directly or through licensing, access to a broad portfolio of intellectual property. The major focus is on product development. Starpharma views itself as a world leader, taking the first dendrimer based drug through the regulatory process for testing on humans.

Starpharma chooses to define its intellectual property in the broadest sense to include its human capital, intellectual assets and intellectual property (as legally defined). The company's human capital incorporates key relationships, skills, creativity, institutional memory and know-how. Intellectual assets include drawings, programs, data, inventions and processes. Legal regimes used to explicitly protect intellectual property include patents, trademarks, trade secrets and copyright.

Alignment with Business Strategy

Starpharma believes that the development of new pharmaceutical entities relies heavily on the effective and efficient creation, protection and commercialisation of intellectual property in the global marketplace. The company considers its intellectual property to be fully integrated with its business strategy, which was emphasized by the Intellectual Property and Commercialisation Manager (IPCM) who indicated:

> *"Matters related to intellectual property are a constant theme in the company's strategic planning and product development processes."*

Starpharma has an adaptable business strategy that continuously evaluates and aligns corporate intent with the evolving nature of the external market. The company has successfully aligned innovation activities with current business objectives.

With reference to business risk, Starpharma indicates that the decision, if and when, to seek legal intellectual property protection is constantly weighed against the cost and benefit of the protection regime. For example, if the risk is in terms of losing competitive advantage, then the benefit to establish formal claims for protection can be justified.

In spite of holding a view that intellectual property such as patents, trademarks etc is a major factor for corporate success, in alignment with the company's broader definition of intellectual property, Starpharma expresses its most valuable asset as being:

"The relationship it maintains with its dedicated employees, followed by its cash resources that allow the company to maintain its R&D activities. Both of these activities are more important to the company than its [legal claims to] intellectual property, recognizing that Starpharma's intellectual property is essential to the future success of the company."

Protection and Management

Starpharma views being the first to successfully deliver a dendrimer nanodrug for human application to market as having greater sustaining benefits than merely owning a rich patent portfolio. In the current uncertain and immature state of the commercial market for dendrimer nanodrugs, Starpharma considers that minimising lead-time to market is a strategy that offers more effective protection over the company's intellectual property than patent protection. Implementation of this strategy is observable through the company's decision to make two early dendrimer products commercially available. According to the IPCM, Starpharma is proactive in its marketing activities. He stated:

"Get Starpharma's name out there to make companies aware that we have the capability to produce materials of that class."

The company views that the progress made, to date, towards achieving this goal, has had significant impact to enhancing the company's reputation and displaying to potential commercial "Big Pharma" partners, Starpharma's technological and operational competencies and capabilities.

Starpharma has a structured approach to innovation; the company has formal corporate plans to pursue and commercialise innovation that are updated regularly. However there is low formality in terms of codified procedures to identifying patent worthy discoveries. The IPCM stated the risk in having prescriptive procedures as:

> *"If you apply a hard and fast rule once, the second time you apply it it's the wrong rule or you've applied it the wrong way; because there are so many elements to consider."*

Rather, Starpharma's approach to disseminating practice around intellectual property is based on developing the corporate culture:

> *"In all of our meetings, IP is a very, very central element to the conversation. It's really embedded in what we do all the time."*

The stages at which their current products and R&D projects are at, ensure that innovation and commercialisation are regular topics of discussion at senior management meetings. Management plays a key role in creating and maintaining a corporate culture that is conscious of the importance of intellectual property.

Structured management of intellectual property in terms of patents and other forms of legal protection is centralised. Starpharma Limited is responsible for coordinating with the relevant management, technical and legal parties in the drafting and filing of patents and trademarks. Starpharma chooses to make initial filings in Australia, and subsequently other major markets, including USA, Europe, China, Mexico, Canada and New Zealand. The company has a strategy to take out broad patent claims and, where possible, with intention to block other players in the field from making challenges into their area of core intellectual competence. A number of dormant patents are maintained in the portfolio for this specific strategic purpose. Regular review of the patent portfolio in conjunction with the current business strategy influences decisions to develop new patents around older patents nearing the end of their life, or to allow other dormant non-strategic patents to lapse.

At this stage, Starpharma's believes that the cost-benefit analysis of trademark and copyright protection of brands suggest that they are not an effective way to protect competitive advantage and, as such, are not a high priority. The company has a current strategy to pursue Common Law protection for trademarks rather than formal legal trademark registration. The reason for this strategy is largely influenced by their

targeted objective to secure licensing arrangements with "Big Pharma", whom they recognise have their own agendas related to marketing matters:

> *"There is no certainty at all that the licensee is interested with the name associated with the product. Because their marketing group may not consider that the name will meet their needs."*

Networks and Collaborations

Starpharma has an enviable absorptive capacity in relation to leveraging technical and market expertise. The company is actively involved in acquiring knowledge and makes contributions to the growing field of dendrimer science. Starpharma's view on their involvement in the growth of the dendrimer field is described by the IPCM as:

> *"Empowering competitive activity though partnerships, in a sensible umbrella arrangement, to work together to solve problems. We have this philosophy of lowering barriers to entry to allow and encourage other companies to invest in the development of dendrimers."*

Executive and Technical members of the firm alike are active participants, formally and informally, within scientific collaboration partnerships, alliances and the wider pharmaceutical community. Such networking opportunities are of significant importance to assist Starpharma in understanding emergent trends in the market and to be able to evaluate and direct its resources to the projects that offer the most successful opportunities. Patent searching and working with specialised consultants are other ways in which Starpharma keeps actively informed of developments in industry and to maintain an awareness of the evolving nature of the competitive landscape.

Starpharma has a broad range of channels through which the company sources intellectual property. Internally, intellectual property generation is achieved through the continual creativity of the company's research scientists. Complementing internal

capabilities, the company extensively leverages external channels, including the acquisition of intellectual property rights via the licensing of intellectual property (via the BRI and DNT) and collaboration efforts through its global research network.

The strategic investment in DNT, Inc. provides Starpharma with access to specialised technical competencies. The structure of the relationship between DNT and Starpharma is such that Starpharma, a core partner for development and commercialization of pharmaceutical applications, can influence the direction of DNT's research and development activities. Starpharma's global research network, spanning widely across Australian, American and European research groups, affords the company similar influence to generate relevant intellectual property. Access to diverse sources of intellectual property serves to accelerate the investigative and product development processes. In addition to intellectual property sourcing, Starpharma's network of contract partners provides complementary capabilities in the areas of testing and manufacturing.

Subsequent to its public listing in 2000, Starpharma has taken significant steps in the allocation of resources to facilitate achieving its business objectives. The company became one of the first to locate a new laboratory and offices within the recently opened Baker Heart Research Building, part of the Alfred Medical Research and Education Precinct, Melbourne. The state-of-the-art laboratories and access to some of the best possible facilities and biomedical resources provide Starpharma the necessary tools to perform best-practice research and development.

A significant proportion of the R&D activities undertaken at Starpharma are based on technology developed by others, for which Starpharma has acquired exclusive patent licences. For the 12month period ending 30 June 2002, Starpharma's total R&D expenses were approximately AUD$6.2 million. The in-house incremental approach to innovation of these technologies is complemented by efforts to invite and integrate skills and expertise from "best-in-class" scientists whose motivation is largely seen in being able to participate in shaping the frontier of an emerging field of science.

From a strategic and operational perspective, considerable human resources have been devoted to organizational and managerial change, specifically in the areas of strategy planning, OH&S training, HR training, and HR restructuring. Two initiatives are of note. First the establishment of in-house management capability for pre-clinical drug development. This is an initiative that aims to increase Starpharma's control over product development projects, with the intention to reduce development time, cost and risk. Second, investment in DNT, Inc. to develop strategic alignment that would be beneficial to both Starpharma and DNT. Starpharma was also able to lend its business and commercialisation expertise to DNT, and will continue to provide advice about the direction of future R&D activities undertaken by DNT.

The marketing of products and services is an activity of significant priority for Starpharma's Executive Team. In addition to the promotion of new product development initiatives, marketing efforts are focused on promoting Starpharma's technological and commercialization capabilities to attract the interest of prospective complementary partners, like "Big Pharma", with significant mass-market marketing and distribution assets. Furthermore, marketing is seen to be a function performed implicitly by all members representing Starpharma publicly in events such as international conferences.

Innovativeness

In the last three years many new product lines have been conceptualised and evaluated by the Starpharma group. The dedicated Intellectual Property management entity Starpharma Limited, as one of its main foci, has to identify new products related to the commercial application of dendrimers as pharmaceuticals and has, for example, identified numerous product opportunities in anti-viral, anti-cancer, anti-toxin and bio-protection applications. The "market-pull" demand mechanism influences Starpharma's approach to new product development opportunities and the company is active in identifying and effecting incremental changes in its product and service lines.

This rate of innovation is common with many of Starpharma's current initiatives, especially since products are still in their relative early development phases; Starpharma's drug products like ViaGel are not yet marketed in the final consumer market and, thus, relatively minor changes are still being made for their eventual application. Currently Starpharma is involved in 7 R&D projects, focused on a wide range of biomedical areas: sexually transmitted diseases, systematic antivirals, biodefense, respiratory disease, oncology, tropical diseases and new dendrimer architectures. Members of the company actively engage in making contributions to the field, through published works, participation in conferences and involvement in nationally and internationally coordinated efforts furthering developments in this area of technology.

The priority placed by countries like Australia and the United States on furthering the field of dendrimer science, coupled with Starpharma's recognised core technological expertise in the field has increased the organisation's ability to attract public funding. This, in turn, positions Starpharma as a 'hub' to access the best talent without losing the IP generated from the collaborative development efforts. Starpharma's global network consists of 10 local and 14 international research groups. Engaging in research and development at this level involves activities that include validating other global work in this area, reverse engineering and coordinating multiple perspectives serves to reaffirm Starpharma's position as a major global player in this field.

Implementation of Protection and Management

The Starpharma patent portfolio, managed by Starpharma Limited, consists of 8 families in the areas of antiviral therapeutics and inhibition of angiogenesis. Currently Starpharma has successfully applied for patents in 5 of 8 patent families in the major markets considered to include Australia, NZ, USA and Singapore. Patenting is recognised to be an essential formal mechanism for Starpharma to establish protection over intellectual property. The ability to identify and evaluate patent opportunities is, initially, handled informally. The company does not have a formal audit process, but regular reviews are conducted on an ongoing basis to understand the intellectual property landscape. Starpharma involves external

consulting partners in major markets, whom are familiar with the field and the current intellectual property landscape.

Starpharma's collaborations with external groups present a challenge to effective management of interactions, in the areas of general scientific processes, and particularly around issues of intellectual property rights and ownership. However, Starpharma reports positive experiences with academic collaborators and national research groups:

> *"Long standing practice of commercial entities owning outright the intellectual property, the National Institute of Health (NIH) [a collaborator in the United States] and other groups are really just interested in rights to publish, under appropriate delay arrangements if required."*

The IPCM indicated that there is an obligation attached to the funding sourced from the United States Government, which maintains a right over intellectual property generated from research funded by the United States Government:

> *"If the Government in the US is sufficiently excited by it [research funded by the US Government] then, in theory, they could effectively force us to take a compulsory license. Their philosophy is very different to Australia, they have this idea that they will fund companies to carry out research of direct relevance to the Government's priorities, and if there are any consequential commercial opportunities that flow over, fantastic."*

The United States Government has the right to force any organization receiving its funding to continue with commercialization developments even when the outcome is not aligned with the company's business priorities.

The field of dendrimer chemistry is still a relatively new and specialised field; there are still relatively few commercial players and even fewer focusing on the applications in pharmaceutical-related development. These current environmental conditions have not made it possible for Starpharma to determine the degree of effectiveness of patent protection.

Starpharma currently enjoys this competitive advantage but also recognises that it is a situation that can turn against them. This is why they place greater emphasis on protecting their position and intellectual property by minimising lead time to market, combined with an emphasis on the management of secrecy and know-how.

Starpharma's current view on trademarks, brand name and product marketing as a form of intellectual property protection is of lower priority and fits less easily with their current business strategy; as their targeted objective is to secure licensing arrangements with "Big Pharma", whom they recognise have their own agendas for marketing matters.

The company considers the maintenance of control over the distribution of key data and information to be of greater importance to protect competitive advantages.

Enabling Business Practices – Systems and Information Technology

Formal systems and information technology are enablers in daily operations at Starpharma. As a company whose activities are based around pharmaceutical product development, strict practices and compliance with regulatory agencies are required. Starpharma's implementation of a quality management system has been specifically developed in compliance with international standards and regulations, including those defined by the United States Food and Drugs Administration (FDA), as well as the Australian Therapeutic Goods Association's (TGA) Codes for Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP). In relation to contract and supplier contributions to Starpharma's product development efforts, the company's quality program extends to assure the quality of input and external service provided to the company.

Use of information technology (IT) is a prominent tool used daily within the company. R&D activities use information technologies for data collection and analysis. The bulk of data generated by Starpharma is the output of rigorous testing at each stage of the pharmaceutical product development process. Implemented quality

systems also make use of information technologies for which the assurance of data integrity is a high priority. Starpharma believes that data accuracy and integrity is critical to reducing product development time.

Staying connected with a global community and in touch with what competitors abroad are doing can be achieved conveniently via the internet; activities such as patent searching, accessing updated scientific and competitor information are now readily accessible through updated online sources. Similarly, the dispersed nature of the organisation's research network relies on cost-effective internet and e-mail based methods to interact and communicate, designs, results and data. Internally, Starpharma's network provides multi-user access to knowledge directories, and manuals for procedures and processes. Investigation of information technology solutions for knowledge management and collaborative project management has been considered to enhance current practices.

Conclusion

Starpharma is a specialised biotechnology company that is focused on developing a base-technology around dendrimers with broad pharmaceutical applications. Unlike major pharmaceutical companies with all the necessary complementary assets to make drug commercialisation realisable, the Starpharma business strategy recognises the need to partner with the right individuals and groups that can offer access to the necessary complementary assets required for successful commercialisation.

Starpharma is organised with a core focus on intellectual property and relationship management; central to facilitating this is the corporate subsidiary Starpharma Limited. A key strength of the company is its operation as a virtual organization; a small permanent workforce that is complemented by an extensive network of collaborators at both the supply and marketing ends of the product value chain. The transient nature of some of the relationships, especially collaborations with specialised scientific researchers, allows Starpharma to attract and work with some of the highest class individuals and groups in the field. Starpharma aligns its core

technology focus on dendrimers science with national research priorities. This allows Starpharma to supplement its R&D funding with public grants from Australia and the United States, and to still maintain control over generated intellectual property.

Starpharma has a broad view of intellectual property, which encompasses codified and tacit knowledge as well as people and relationships. The company has the view that without human and fiscal resources to commercialise intellectual property there would be little value to the organization. The company believes that it is important for its corporate culture to be diffused with values based on intellectual property. Its influence over all functions and roles adds a valuable layer of protection over the company's intellectual assets.

Starpharma recognises that legal claims over intellectual property are fundamental. The company has an understanding that is consistent with the sector. These mechanisms are essential factors in the product development process, to accelerate the process from concept to market.

Implications for Managers

Intellectual property is a key factor in generating competitive advantage for biotechnology companies. An important implication for managers that has emerged from the case study is that protection of intellectual property alone though legal regimes like patents cannot lead to successful commercialisation. Investment into legal claims over intellectual property needs to be considered together with business strategy and business risk. Other methods of protecting intellectual property, like secrecy and management of know-how represent effective forms of protection not to be overlooked; equally deserving of management and capital commitment.

It is important that all businesses recognise that they need an IP strategy to commercialise their products successfully and avoid pitfalls. Some of the key elements in developing an intellectual property strategy are:

- ensure that the firm’s ideas are new and avoid infringing the rights of others by searching the patent and trademark databases;
- instil a first to market philosophy in the corporate culture;
- develop an infringement strategy;
- educate staff so that confidentiality is an espoused value;
- establish a link between the intellectual property system and the company’s business strategy;
- IP assets must be identified and valued to ensure that they are itemised in your business plan.

TextileCo: imported and manufactured home textile products[4]

TextileCo is an Australian Company which manufactures and also engages substantially in importing home textiles, nearly exclusively of the non fashion variety. These include bed linen such as sheets and related items, pillows, pillow cases as well as curtains, towels, carpets and other soft home furnishings such as cushions. In addition, on an opportunistic basis, the company arranges for contract manufacturing either inside or outside of Australia of items such as tables, chairs, umbrellas and other similar furniture stock. The company has sales of approximately AU$50 million per annum and is profitable. It is currently a second generation Australian company some fifty years old in its present form. The founder of the company has retired but sits on the board and his son is currently Managing Director, in charge of some AU$10 million of assets and fifty people in total.

Intellectual property in TextileCo

The company exists mostly as an intermediary between the producers of soft home furnishings and textiles, which are located in countries such as Pakistan, India, Indonesia and increasingly China, and the major and minor retailers in Australia and New Zealand. As an intermediary that places orders on those international suppliers and manages complex and challenging relationships with demanding retailers, this company must constantly strive to add value and avoid disintermediation. Disintermediation would involve the company's customers going directly to its suppliers, which is always a threat. Companies such as Woolworths and Coles Myer are constantly attempting to increasingly get into the business of "Direct Import" which would indeed disintermediate TextileCo. Additionally, full service providers are now making themselves available to Australian retailers, especially large ones which will provide the service of sourcing, transporting, distributing and even pre-pricing and customising the packaging of products such as sheets, towels and, indeed, clothing for these retailers. The competitive position of these companies is in providing a very high level of service and support to the retailers. Some of them are based in China and Pakistan, and they have massive scale across categories.

[4] This case was written by Professor Danny Samson, University of Melbourne

The competitive strategy of TextileCo is to provide good reliable service at competitive prices. The company attempts to differentiate itself by providing good service whilst keeping its costs down and hence being price competitive. The service takes many forms including simply high levels of DIFOTIS (percentage of orders delivered in full on time in specification). Known as a reliable supplier, TextileCo has a reputation for pulling out all the stops in order to meet customers requirements; when a supplier in China or Pakistan lets TextileCo down by failing to ship goods in time or shipping defective goods, then TextileCo is known for its strenuous efforts to overcome such difficulties, for example, by air freighting the product into Australia in order to ensure its retail clients' shelves are well stocked. TextileCo also provides, as part of its service based differentiation, highly innovative and attractive designs. Particularly with bed linen but also with other categories of soft tone furnishings, fashion and well styled designs are an important driver of the volume of sales in retail stores. The expertise and flare for knowing good design from bad and being able to merchandise and package, and produce a well designed product is a distinctive competency of TextileCo.

TextileCo has an innovation strategy that is therefore linked to the nature of the service that it provides, mainly differentiation through good design. There are other suppliers who may be able to undercut it price and therefore win in the commodity end of its markets, but do not have an investment in a design facility that matches TextileCo's. When retailers want well designed products they know that TextileCo can deliver. Indeed, TextileCo is often proactive in this regard in designing new ranges of product and taking these designs through a selling process to their retailers.

Much of TextileCo's knowledge is tacit and explicit process knowledge held closely by the two or three most senior managers in the company. They protect it not by patenting it, which means some degree of disclosure, but by keeping it to themselves.

The Intellectual Property Core of TextileCo

As part of its business strategy TextileCo is innovative, and as part of its innovation strategy, TextileCo has intellectual property in the form of its design and design

processes. However the totality of intellectual property of TextileCo is much deeper and broader than its design expertise. TextileCo exists because of its know-how which is clearly a form of intellectual property developed over some thirty plus years. The senior executive's of TextileCo, including the founder, his son and one other key General Manager, have developed and refined their know-how at managing a number of important processes. These processes keep TextileCo competitive and, therefore, keep them alive and in business, in what is very much a hypercompetitive and indeed cut throat industry.

TextileCo is wedged between powerful retailers and large international suppliers thousand miles to its north. The retailers would like to capture TextileCo's slice of the value chain and, over the past fifty years, they have regularly tried to do so by engaging in bouts of direct importation. However, the main reason that, to date, they have always come back to TextileCo as a stable and regular supplier, is due to the expertise that the retailers have neither been able to match nor develop. This is the core intellectual property (IP) of TextileCo. The intellectual property of TextileCo is specifically manifested as "know-how" and it pertains to the effectiveness of the important value adding and support processes within the company and across its boundaries.

These forms of IP are:

1. Design - TextileCo is lean and efficient, yet, at the same time, effective in producing original designs and adapting designs that it sees overseas and in other places to the categories of merchandise that it controls and sells. TextileCo executives are very consistent and regular attendees at international fairs, shows and conferences, and they keep closely in touch with international trends in designs, colours, materials etc. The design department comprises four full time staff, who are professional designers, and a significant investment has been made in design software, workstations, high quality printers and related technologies.

2. TextileCo's supply chain is very lean. The supply chain from countries such as Pakistan and China involves finding reliable and very cost effective mills which will produce large volumes of items, such as sheets, pillow cases, towels, quilts etc, to the customised requirements of TextileCo and its clients, at very competitive prices.

These also need to be shipped to Australia in a timely fashion with the correct packaging and labelling made to specification. TextileCo is long experienced and very expert in managing these long distance supplier relationships. They are not trivial. This is an important form of know-how that would be difficult to replicate efficiently in either a start up company or even in a major retailer.

3. Client relationships with major and minor retailers is another strong area of expertise and know-how within TextileCo. The company has developed these relationships such that it has a very strong reputation in the industry and it knows intrinsically how to market and how to sell to retail buyers, even though these retail buyers are often pressured to disintermediate importers and local manufacturers.

4. Stock management is another area of importance to TextileCo. Their process knowledge includes stock rotation, elimination of old and unsold stock, attempting to maximise inventory turns while still keeping high levels of DIFOTIS, and the technical aspects of stock management, record keeping, warehouse management and related processes.

5. Quality assurance is an important part of TextileCo's activity. Retailers have stringent standards and will return large batches of stock if they detect any quality problems. TextileCo, therefore, has remained quality accredited, but it far exceeds the minimum standards of such formal systems by ensuring it tightly controls quality of its supply chain.

6. Marketing is an important part of TextileCo activity and this includes pricing, costing and simply, selling well.

The intellectual property at TextileCo involves mostly its process knowledge, and that is process knowledge of the key activities that keep it in business in addition there is IP associated with its actual designs and its use of information.

Concluding Remarks

TextileCo is a case of a relatively small company, of some fifty people with a value added of only $20 million of its $50 million sales, from which it generates a profit

through the cleverness of its executives and the dedication of its staff in the way in which they manage the organisation's boundaries. This principally means that the company stays in business because it "buys well and sells well". This involves intellectual property as process knowledge in terms of the know-how principally of its executives but also of the many support staff that implement the processes within the company.

TextileCo uses an IP strategy of "running", meaning that it tries to stay ahead of its competitors, not using any formal IP protection mechanisms. This is because of the administrative work required to do so, the ease of cloning, copying or producing very similar designs, with almost identical designs in this industry, and the 'need for speed' in the market place, in which designs move and change fast.