Management Online REview

Insight and Best Practices in Biotechnology Commercialisation

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Abstract

Successful commercialisation of academic research is of great importance to the development of a strong economy and subsequent re-investment in skills and infrastructure. The biological and medical sciences area has been shown to contribute a significant proportion of global research and development expenditure resulting in a high level of activity and competition amongst researchers to commercialise their work. This article reviews best practice in commercialisation and presents a model which will inform those seeking to improve the prospects for commercial success.

Keywords: Biotechnology commercialisation, Technology transfer, Biotechnology, Venture capital, Imperial Innovations, University of California San Diego

Introduction

University researchers were hired and extensively utilized for laboratory research on United States government projects during the First World War. This strategy was however changed during the Second World War when the government chose to partner with education institutions in the form of contracts, thereby allowing scientists to maintain some control over their research activities (Geiger, 1990). In 1945, President Franklin D Roosevelt of the United States of America received a report by Vannevar Bush. In the report, Bush stressed that medical progress was directly dependent on continued research progress by university scientists (Bush, 1945). In the late 1940s, and in recognition of the immense contributions of academic scientists during the Second World War, the American government increased the support it gave to science research (Bok, 2003). As a result, several faculty research personnel chose to remain in academic research instead of veering off into industry. The expertise and intellectual capital that they possessed were crucial to the successes achieved in science between 1940 and 1970 (Geiger, 1990). By the end of the 1960s, the United States of America was undisputedly, the global leader in technology development, and university research was at the centre of this revolution (Bok, 2003). This has been explained as being a direct result of the three decades of increased government funding leading to expansions in faculty research interests, boost of graduate school education and salary

payments to laboratory technicians and support staff and also the purchase of costly research facilities (Geiger 1990).

Aims

The aims of this paper are:

- To review the available literature and identify the factors impacting on the commercialisation of academically generated biological sciences innovation;
- To impose a best practice model for commercialisation, including internal and external factors to inform decision makers and stakeholders.

History and Trends

The Bayh-Dole Act of 1980 by the United States Congress was the originating factor for the commercialisation of academic biotechnology (Bayh-Dole Act, 1980). Its central aim was to enable academic institutions to lay claim to the Intellectual Property that arose from their discoveries which had been funded by federal funds (Schmidt, 2002). Before Bayh-Dole, there was no structured technique for the commercialisation of biotechnologies discovered under federal government funding. By the mid 1960s there was obviously an increased government funding of biotechnology research by the means of grants by entities like the Department of Energy (DOE), the National Science Foundation (NSF), the National Institutes of Health (NIH) and the Department of Defence (DOD). Goodwin (1996) believes that because academic research led to a significant rise in the development of novel techniques and knowledge (with the attendant positive implication for the nation's economy) such funding was considered to be in the public interest.

In 1980, with the Bayh-Dole legislation in place, academic technology transfer commenced with just about 25 universities. By 1992, this number had reached 200. In fact, the Bayh-Dole Act was only the first in a series of federal legislation that enabled academic institutions to encourage industry participation and the commercialisation of their technologies (Slaughter & Leslie, 1997).

A subsequent piece of legislation was the Small Business Innovation Development Act of 1982 which demanded that 2.5% of spending from federal agencies having a research budget of over one hundred million dollars be set aside for research into small businesses. Large research institutions argued that these funds should be made available to them for fundamental research. However, by the mid 1980s, United States federal policy had experienced a shift, enabling academic institutions to engage in "academic capitalism" (Slaughter & Leslie, 1997). Faculty became able to engage in more commercially oriented research and gradually began avoiding research projects which were driven by mere curiosity (Etzkowitz & Leydesdorff, 1997).

Today, academic institutions and smaller companies have fashioned a complex structural technique for the transfer of these academic technologies to spin off companies where universities share in the resulting royalties. Typically, such businesses emerge from the inventions of academic research. Federal grants are given to nascent businesses which have the researchers as the Principal Investigators and the academic institution as the business partners (Gaither, 2003). Nevertheless, these kinds of interplay have resulted in financial conflicts of interest and issues of eligibility of the Principal Investigators even though they are supported by federal grants. In the early 2000s, research grants for small business awarded by the federal government were no longer awarded to businesses which where primarily owned by Venture Capitalists. The effect was of major significance because in 2002, under the Small Business Awards, 1.5 million USD was awarded to five thousand companies by the United States government (Gaither, 2003).

Ernst & Young reported venture capital funding rounds for US companies were rising steadily from 1996 to 1998 (195 rounds) and declining in 1999 (185 rounds). In 2000, the rounds rose to 304. During the same period, venture capital investment values changed from 1383.41 million USD in 1998, 1799.56 million USD in 1999, to 4101.18 million USD in 2000 to 3296.22 million in 2001 and 2 790.05 million USD in 2002. (Ernst & Young, 2009).

R&D Spending in the US and Academic Medical/Health Centres

Munteanu (2010) reports that R&D spending in US biotechnology companies has risen remarkably from $4.6bn in 1970 to $30.3bn in 2001. The report further states that unemployment levels have also risen since 1992 from 79,000 to 191,000 in 2001. In addition, the total number of firms has grown to 1457 from 1271 during the same period.

In the 1990s, there was a massive 40% increase in the reimbursements for health insurance for academic health centres from the typical reimbursement rate. This extra money took care of academic biotechnological research including the wages of both faculty and support staff as well. With managed care however, the reimbursement rate plummeted dramatically and the extra funds from insurance disappeared. The result was a sudden 50% reduction in the academic revenue. The Academic Health Centres were thus, in the red (Van Der Werf, 1999). A vivid example of this scenario was with Loyola University Chicago. It was one of the wealthiest Jesuit colleges in America in 1993 (its endowment was as high as 450 million United States dollars, it was opening new centres in suburban communities, had a financial Academic Health Centre and over 150 programmes on offer). By 1995, Loyola was in ruins. Its medical centre was unable to break even. It had lost almost 30% of its nearly 450 million endowment value and enrolment had plummeted by a massive 15%. Tuition had also risen by nearly 80% (Van Der Werf, 2000). Subsequently, Academic Health centres struggled to resolve shortfalls. Van Der Werf (1999) reports that some institutions like Tulane University even sold their teaching hospitals outright. Some others consolidated by forming mergers in their health systems (as was the case with the University of San Francisco and Stanford University). Some of these mergers later resulted in losses of billions in money and dissolution of the partnerships with time (Mangan and Blumenstyk, 2000).

As at the beginning of the new millennium, Academic Health Centres were still in search of useful solutions to their funding difficulties. The case of Loyola University, Chicago was definitive, that it led to a complete restructuring of the whole university. The creation of an entirely private subsidiary was Loyola's inevitable solution to an entire financial meltdown. The university closed degree programmes which were dependent on funding emanating from the excess funds from the health centres. Loyola's endowment also had to focus attention on fundraising instead of counting on excess funds from the Academic Health Centre incomes (Van Der Werf, 2000). However, Powers (2006) believes that over 50% of academic research institutions constantly experience negative balances on matters of technology transfer. The report further claims a rise in conflicts of interest with regards to technology transfer. Powers (2006) thus classifies the anxiety towards the commercialisation of biotechnology as irrational. A possible explanation for the conflicts and problems according to Rogers (2003), is the possibility that technology transfer facilities tend to become rather complex with time, leading to a later realization (by the academic institution) that the system is rather complicated and tasking. Interestingly, 28% of the medical device companies in the United States are located in California, with a significant concentration in San Diego. This sector accounts for $3.2bn in NIH grants, $12.8bn in wages and $2.8bn in private research (California Healthcare Institute, 2010).

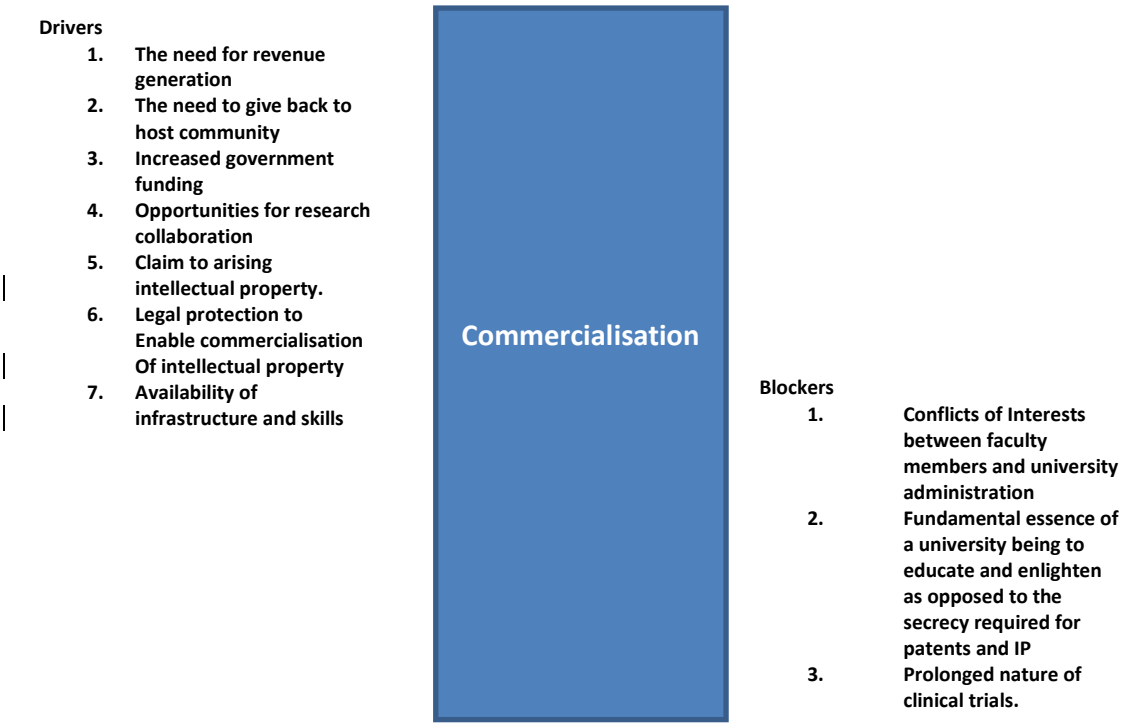

Fig 1. Drivers and Blockers of Commercialisation (Onyeka and Reid, 2010)

Best Practice Models

United States- University of California, San Diego

In 2009 more than 60 companies and organizations offered over 200 products derived from UC San Diego innovations. The companies represent industry segments in biotechnology and the products include: Elmiron® (Ortho-McNeil-Janssen Pharmaceuticals, Inc). ERBITUX® (ImClone Systems (a wholly-owned subsidiary of Eli Lilly and Company) and Bristol-Myers Squibb Company), CytoTrap(Agilent Technologies), Chromatin Assembly Kit (Active Motif).

According to the Technology Transfer Office at the University of California, San Diego, in FY2009, intellectual property income was approximately 27.1 million USD. This income included nearly 22.2 million USD in license fees and royalties, 491,000 USD from fees for copyrights and transfers of tangible research materials and approximately 4.4 million USD in patent cost reimbursement. The University of California, San Diego (UCSD) model recognizes that venture capital and Initial Public Offerings (IPOs) are crucial sources of funding for biotechnology companies. Distribution of funds received by such means is done strategically and in rounds. Subsequent rounds tend to be dependent on previous ones. Most important in such scenarios is the success of product trials. Venture Capitalists tend to work on minimal risk opportunities and as a result, invest in early stage and expansion stage organisations.

Investee organisations typically receive more early stage funding than they do for later stage discoveries. The average first-round financing rose from 3.8 million USD in 1995 to 4.7 million USD in 1998. The average second round funding rose from $4.2 million to $5.5 million in the same period. However, Venture Capital investment in San Diego's biotechnology sector rose from 144.7 million USD in 1990 to 2.185.2 million USD in 2000.

In the same period, Munteanu (2010) reports that the amount raised via Initial Public Offerings increased from 3.3 million to 981 million USD.

The UCSD model possesses five major components, namely:

1) Efficiency of organisation founded on the small size of the university and its flat hierarchy
2) A significant high distribution of research funds to faculty members
3) A significant culture of entrepreneurship
4) A very integrated curriculum in the Life Sciences programmes
5) A tailor-made commercialisation program for biotechnologies including
    a. expertise in research and development
    b. new technology development funding
    c. a launch pad for the development of new companies
    (Milken, 2004; 2006)

United Kingdom - Imperial College, London

27,000 of the 73,000 pharmaceutical industry employees in the United Kingdom are in Research and Development. Their gross output is estimated at about 463,000 USD per person. This accounts for the UK's ranking as the most mature biotechnology industry in the whole of Europe, laying claim to approximately 41% of the public biotechnology companies in the European Union. In 2006, the revenues of the UK biotechnology industry were put at 8 billion USD and 2 billion USD in equity (BIO 2008).

London's Imperial College launched over 50 companies via its technology transfer facilities, making it one of the United Kingdom's most successful in research commercialization (Searle *et al,* 2003). The college signed a 15 year contract with Imperial Innovations in 2005. Imperial Innovations has had a series of landmark achievements including *Thiakis* as its first major exit with a potential to generate 16.1 million GBP from 1.5 million GBP investments. Imperial Innovations has also invested 14.4 million GBP in 20 companies and raised 30 million GBP between 2007 and 2008 through the private placement of shares. Other exits include *Inforsense* (5.3 million GBP), *Circassia* (17.25 million GBP), *Nexeon* (14.25 million GBP), Ceres Power (4.0 million GBP), *Veryan* (5.3 million GBP) and *Respivert* (13.0 million GBP). Interestingly, by the end of 2009, Imperial Innovations had sold *Thiakis* to Wyeth for 100.0 million GBP (Imperial Innovations, 2009)

Imperial Innovations is listed as having the following components:

- Exclusive access to world-class innovations in science and technology from Imperial College, London
- Thriving portfolio across life sciences, clean energy, engineering and IT
- An active operating business focused on value creation through licensing and spin-outs
- Investment provision, management expertise, recruitment and incubation
- Strong team, experienced in science, technology, management and investment (Imperial Innovations 2009).

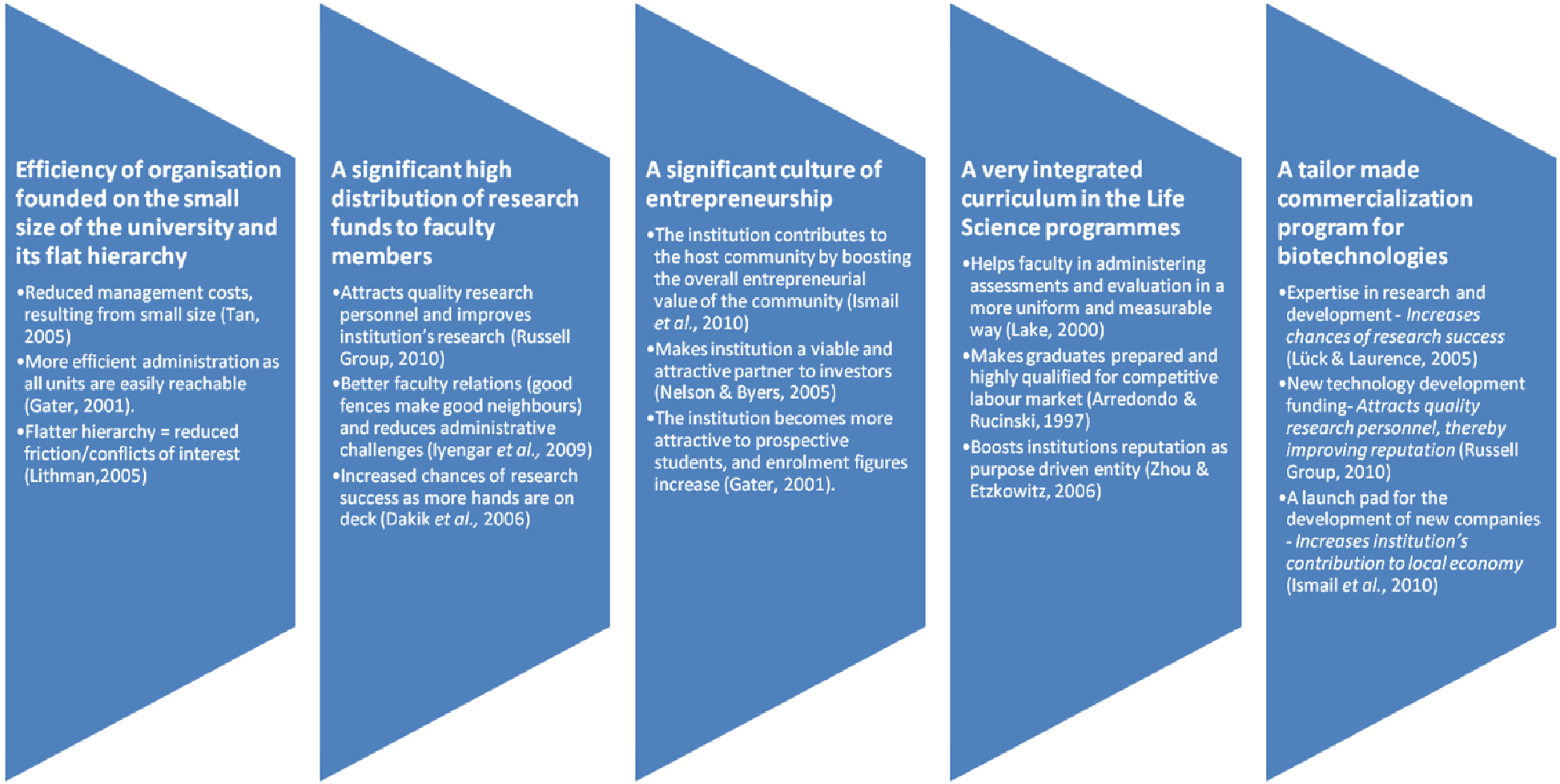

Fig 2. UCSD Model Components and Implications

PUBLICATION	ATTRIBUTE DESCRIBED									
	Small University Size and Hierarchy	Access to World-class Innovations from Host Institution	Entrepreneurship Culture	Integrated Curriculum in the Life Sciences	Cross Functional Network	Partnerships	Active Operations	High Distribution of Funds to Faculty Members	Contained Diversification	Tax Relief
Arredando & Rucinski (1997)				♦						
Dakik *et al.* (2006)		♦	♦				♦	♦		
Gater (2001)	♦									♦
Ismail *et al.* (2010)			♦				♦		♦	
Iyengar *et al.* (2009)	♦							♦		
Lake (2000)				♦						
Lithman (2005)	♦					♦				
Lück & Laurence (2005)		♦								
Nelson & Byers (2005)						♦				
Russell Group (2010)						♦				
Searle *et al.* (2003)	♦				♦	♦				
Searle (2008)		♦	♦		♦	♦	♦			
Tan (2005)	♦	♦								
Zhou & Etzkowitz (2006)				♦						
	Internal Factors					External Factors				

Table 1. Summary of Best Practices (Onyeka and Reid, 2010)

Conclusion and Recommendations

Initial Public Offering amounts, employee numbers and revenue have been identified as the affecting success probability in small organisations. The qualities of research portfolios are now measured by the ability of the concerned firms to raise significant IPO amounts. This has been identified as an indication of a higher probability of future success. Higher revenue coupled with higher employee numbers show that the organisations have better research and development potential.

Universities and other institutions need to transfer and commercialise their discoveries. For successful commercialisation, the following components have been found to be crucial:

1. A small institution size and simple command chain
2. Industrial relevance through partnerships with industry by way of conferences and resource seminars
3. Engagement in world-class research, resulting in world-class discoveries
4. A clear business drive and focus
5. Constant and active commercialisation activities fuelled by a need for relevance and the demand for services.

Interestingly, in addition to the successful commercialisation of nascent technologies or the licensing of spin out companies, these components are mostly internal factors. Tables 1 summarises the internal and external factors which can influence the chances of successful commercialisation. Administrators and managers have significant ability to influence and shape the internal factors and so reap longer term commercial advantage for their institution.

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