Commercialisation Strategy in Biotechnology Start-ups

A thesis presented in partial fulfillment of the requirements for the degree of

Doctor of Business and Administration

at Massey University, Palmerston North, New Zealand

Margaret Janette Dixon

2009

Abstract

The biotech sector has accumulated losses of around US$40 billion since its inception in the mid-1970s. The reasons for this may lie with the science itself, with organization and strategy, with the underlying costs of developing biotechnologies and/or with the institutional environment that biotech firms operate within. This thesis assumes that better organization and commercialisation strategy will improve overall returns in the biotech sector and asks the fundamental questions 'how do biotech firms do strategy?' and 'how can biotech firms do strategy better?'

Strategy is the domain of the strategic management literature. Contributions to the literature that bear directly on commercialisation strategy in the biotech sector are examined. The sector's unique institutional context is found to create an environment of high-risk and high-uncertainty. The real options reasoning and dynamic capabilities literatures provided some useful ideas for strategy in this context. Overall, the literature identifies a shortfall in directly actionable advice for biotech practitioners. Thus, the 'great divide' between academic research and practice is discussed. This thesis seeks to narrow the gap by synthesizing academic theory and practitioner knowledge on commercialisation strategy in the biotech sector in the way that will extend the strategic management literature and provide a process to aid practitioners in strategic decision making.

A two phase methodological approach is employed that begins with a historical review of the development of the biotech sector and three in-depth case studies. Strategic issues facing biotech start-ups at the industry-level and firm-level are examined and related to the business models that firms adopt as an embodiment of their commercialisation strategies. A solid understanding of this relationship is then combined with real options reasoning and theory on dynamic capabilities to propose a model that may help biotech practitioners improve their approach to commercialization strategy. The model is refined and validated in a second phase of research involving interviews with seasoned veterans of the biotech sector. The Commercialisation Options Model is the final output of this research.

Acknowledgement

This doctoral thesis has been one of the great journeys of my life so far. Embodied in the following two hundred-odd pages my thesis only does partial justice to that journey. So, within this preface I'd like to describe the academic and personal voyage I've made over the last eight years, and to acknowledge those that have helped me survive it.

On embarking on this doctorate in early 2002 I was both a seasoned entrepreneur and had served as a professional corporate executive. I was also a wife and a mother of two. My beautiful daughter was three years old, and my son was yet to celebrate his first birthday. My wonderful husband had quietly suffered through two earlier business degrees and a five year diploma in medical technology. I was an executive in a pharmaceutical manufacturing company, not realizing that within a few years I'd be at the helm of a massive restructuring project that would see me and three quarters of my staff retrenched. Before this thesis was completed I had seen myself through one career, and had embarked on another. I had established two start-up biotech companies in the field of drug development. I was putting into practice the learning from my doctoral research before I had even fully articulated them in this thesis. I began my doctorate as an outsider to the biotech industry, but by the time I had completed it I was fully an insider.

Whilst I was a 'professional part-time student' by the time I began my DBA I was still unprepared for the roller coaster ride of doctoral research. I have 'wandered around in the wilderness' many a time over the last eight years, but throughout that time some things have never changed. I have always been interested in the biotech industry, always been interested in commercialization strategy, and always wondering how 'we' biotech entrepreneurs could do a better job. I have a passion for science and a passion for business, but my own early entrepreneurial experiences had shown me this wasn't enough! Good ideas were still hard to bring to market. I also have a passion for learning new things – so out of my entrepreneurial frustrations and my lust for new knowledge was born the beginning of a doctoral thesis. The initial topic was very nebulous, and in non-academic terms was expressed as "how do you make

money out of biotech"? My focus was on commercialization strategy because commercialization is the process by which innovation is brought to the market place. Commercialization strategy embodies the most crucial decisions a firm makes in terms of its ability to make profits.

I was introduced to the strategic management literature early in my doctoral voyage, as part of the mandatory coursework that was to prepare me for being cast out into field research. The strategic management literature *felt* like the right place to start, because after all, I was interested in strategy! Much to my surprise the strategic management literature had very little to say about 'commercialization strategy' per se. And whilst many of strategic management's core paradigms appeared useful, none seemed to fully explain or capture the complexity of commercialization in the small, entrepreneurial, resource-strapped biotech firm.

Early on in my studies (the first five years or so) I was not very clear exactly what my research question was – in academic terms that is. I *knew* we needed to do biotech commercialization better because although the scientific frontiers were full of promises for dramatic improvements in human morbidity and mortality, the biotech sector was racking up billions of dollars in losses. I *felt* that there were answers to be found, but it soon became obvious that they weren't to be found exclusively in the strategic management literature. So it was early in my journey when I first perceived a gap between academic knowledge and the needs of practitioners. However, it was many years before I fully realized that I could make an academic contribution by narrowing that gap in one small niche. The commercialization of biotechnology was a niche that I am passionate about, but it is also of significant interest and importance to other stakeholders in the biotech community – including scientists, entrepreneurs, investors and patients.

An exploratory case study seemed like the right approach to trying to define exactly what it was we needed to know about biotech commercialization. I'd like to thank Professor Steve Henry for the many many hours of precious time he gave in helping me to understand every facet of his biotech start-up and its strategies. One exploratory case study lead to another and then another. I had collected so much data on every aspect of commercialization and strategy in my three case studies that I was

becoming paralysed. However I had also realized that biotech entrepreneurs *collectively* had a wealth of knowledge about biotech commercialization. Each had some pearls to offer, though none knew it all.

With a better understanding of small entrepreneurial biotech firms and the strategic issues they face it was time to turn back to the strategic management literature for some help – what strategies could biotech firms adopt to successfully commercialize their technologies in the face of their specific issues? As no two biotech firms are exactly the same and because they operate in (often) rapidly changing environments I came to the realisation that 'pre-packaged' strategies were not going to be a solution. Rather, what we needed were processes to follow, that would provide guidance no matter what the technology, market or environment looked like. And we needed processes that would be flexible and allow commercialization strategies to adapt to changes both within the firm and within the firm's environment.

Real options reasoning and dynamic capabilities were two areas of theory within the strategic management literature that resonated strongly with me in terms of contributing processes that would help biotech firms to do strategy better. In the end I have combined the academic knowledge in these areas with the practitioner knowledge I've distilled from my case study research.

I initially sought to follow a grounded theory approach in my case studies – observing, describing and interpreting. However, as I increasingly became an industry 'insider' as my research progressed, I moved away from grounded theory and have adopted an interpetivist / constructivist approach. I have sought to combine academic and practitioner knowledge in order to enrich the strategic management literature and to provide biotech entrepreneurs with useful guidance for improving commercialization strategies. I am a biotech practitioner and I believe my own knowledge and intuition has enriched the solution. Whilst this approach is rather unusual for a doctoral research project I believe it is appropriate in terms of my goals to narrow the gap between academia and practice.

The ultimate outcome of this thesis has been the proposal of a model for commercialization strategy that may be of value to biotech firms in building flexible

strategy in facing their many strategic issues. The model has been built on verifiable research, and tested by experts from the biotech community. It is not perfect – there will always be room for improvement through successive iterations between developing academic understanding and practitioner experience. However, doctoral research has a deadline. I have drawn my research to a conclusion that serves the needs of both academics and practitioners.

It has been a long journey and I would like to thank several people who have been instrumental in helping me reach this destination. First and foremost I am deeply grateful to my husband Mark who has provided his whole-hearted support and encouragement over many long years, and to my children Ashley and Russell who have given up a lot of their childhood 'mummy time' even though they had no say. I'd also like to thank my supervisors, Professor Ralph Stablein and Dr William (Bill) Kaghan, who have provided me with direction and inspiration from beginning to end. Thankfully they have understood me and not tried to make my research fit some conventional template. Rather, they have encouraged me on my own eclectic path, guiding me in order to shape my final output into something that would be recognized as a thesis. Extra thanks to Bill for recognizing that he could not convert me into a sociologist, although it seemed he never gave up trying. Finally, I wish to thank everybody who participated in my field research – who generously gave up their time and shared their confidential strategies with me, or provided their valuable critique of my emerging model. It has been a tremendous personal opportunity to learn vicariously through sharing their experiences.

I hope that all I have captured and documented in this thesis will in turn be of benefit to others. I sincerely believe the biotechnology industry will work through its early teething issues and in the future will contribute profitably as well as productively to the benefit of mankind.

Table of Contents

List of Figures

List of Tables