1. Introduction: innovation and entrepreneurship

INTRODUCTION – SCOPE OF THE BOOK

This book fills a market need in the fast-growing area of biotechnology management. Its key focus is the area of entrepreneurship and innovation in biotechnology, as it covers the main theoretical and practical aspects concerned with entrepreneurship in the biotechnology industry, focusing particularly on the innovation processes that underpin success for new biotechnology firms (NBFs). While the physical size of such companies may be small, resourcing and financing issues associated with major long-term R&D programmes are significant, as are potential returns. Entrepreneurship and innovation are major factors in all stages in the development of such companies; however it has been recognized that the biotechnology industry globally is lacking in managers and researchers with appropriate entrepreneurial and commercial skills (Batterham 2000; Sainsbury 2002).

The importance of the area is demonstrated in the priority afforded to entrepreneurship and innovation by universities, public sector agencies, governments and industry globally.

It is intended that this book will assist the reader to develop:

● The ability to differentiate between innovation and entrepreneurship in the biotechnology context;
● The ability to define the various forms of innovation present in the biotechnology industry;
● A detailed understanding of the strategic role of innovation, R&D and intellectual capital in biotechnology organizations;
● The ability to evaluate the impact of cycles on the competitiveness of biotechnology organizations and to make some predictions on these impacts;
● An ability to assess the external environment of biotechnology organizations from a scientific, regional, policy and resource perspective;
● The ability to define networks and alliances in the biotechnology industry, and assess their suitability in defined contexts;
An appreciation of the impact and importance of globalization in the biotechnology industry and to biotechnology companies in terms of competitiveness and the imperative to innovate.

The book explores the role both entrepreneurship and innovation play in the competitiveness of biotechnology companies. Entrepreneurship is considered in terms of individuals/groups recognizing and acting upon opportunities in biotechnology-related markets. Innovation is viewed both as a creative process and as an essential element of an effective management structure and strategy for achieving growth in a biotechnology company. The book focuses on innovation and bioentrepreneurship in the biosciences side of the biotechnology industry rather than the more specified areas of agricultural or environmental biotechnology in order to maintain a balanced international perspective.

The book reflects two critical aspects for consideration of the entrepreneurial biotechnology company; the first with a company focus (internal environment), the second considers the position of the company in the biotechnology industry (external environment).

These two aspects highlight the importance of innovating to compete in the rapidly developing, technically sophisticated, biotechnology industry. The NBF must develop a market presence through an entrepreneurial orientation and innovative products, or research programmes, contractual services and internal processes, while avoiding operating in isolation.

It is the intent of the authors to reinforce the premise that entrepreneurship and innovation are key to achieving and maintaining competitiveness in the biotechnology industry. As in any industry, there are general management principles that apply alongside the specifics of the industry. These follow roughly an 80/20 rule; 80 per cent of management issues are generic across industries, but it is the 20 per cent that are unique to an industry that makes the difference. Knowledge of one of these components alone is insufficient; a combination of the two is required for successful management – in this case, in the biotechnology industry. This book combines both the generic and the specific management issues as much as possible, but its emphasis on matters of direct relevance to the biotechnology industry from an internal and external perspective is what makes it unique and distinguish it from other more generic texts on entrepreneurship and business.

Practical application to support the theoretical concepts is achieved through the many and varied case examples employed throughout the book.

The case studies and case examples take an international perspective. Such a perspective recognizes that best practice examples emanate not only from the USA where the biotechnology industry is more mature, but also from emergent industries in other countries. Much existing material originates
in the USA and relies on the United States’ unique (but not necessarily transferable) capital market structures and the free movement of activities from universities to the private sector supported by legislation such as the Bayh–Dole Act and the Stevenson–Wydler Act. The impact of measures such as the Bayh–Dole Act’s ‘use it or lose it’ edict for university intellectual property (IP), are unique to the USA and are only under early consideration in most other countries. Although the USA does provide many examples of best practice due to the advanced nature of its biotechnology industry, each national industry environment is unique and lessons and practices are not necessarily directly transferable. There are a number of other examples of attempts to develop biotechnology policies nationally, for example South Korea and Singapore, which have instituted nationwide biotechnology policies, as well as publicly-funded support mechanisms. Singapore has expressly established biotechnology as one of its economic pillars (particularly when a previous pillar, the IT industry, collapsed). Cases are drawn from Australia, New Zealand, the UK, mainland Europe (including Germany, Denmark, Sweden, France and Switzerland), Asia (including Singapore, South Korea, India and Taiwan) and the USA, to highlight examples of different entrepreneurial biotechnology firms, and the industries in which they operate, providing a multiple perspective that avoids a single lens for analysis. The book therefore provides a very different perspective to conventional US material.

There are considered to be three distinct areas of biotechnology:

- Red – Biomedical, medical and human health (and animal health)
- Green – Agricultural biotechnology
- White – Industrial biotechnology

The emphasis of this book is on Red biotechnology, emphasizing human health, life-prolonging, life-preserving and life-improving technologies and developments. This in no way seeks to place Red biotechnology above Green or White; it simply displays the orientation of the authors’ knowledge base.

INNOVATION

Innovation is a complex concept as there are a number of forms of innovation. The general definition is presented here followed by the more narrow definitions. Innovation in its widest sense is considered to be anything that is new to a business (Abernathy and Utterback 1978). The traditional concept of innovation is well documented and defined. In fact it has been defined, particularly for technological innovation, to such a degree that
survey questions have been standardized in the OECD’s Oslo Manual (1997, p. 31) which states, ‘technological innovations comprise new products and processes and significant technological changes of products and processes. An innovation has been implemented if it has been introduced on the market (product innovation) or used within a production process (process innovation)’.

Innovation plays an important role in organizational and economic development, as evidenced by the large scope and sum of dedicated literature. It can be found in such areas as management (Damanpour 1991; Van de Ven 1986), learning (Cohen and Levinthal 1990; Nooteboom 1999), strategy (Lengnick-Hall 1992), clusters (Kenney and von Burg 1999; Poudar and St John 1996) and networks (Diez 2000; Robertson et al. 1996).

Furthermore, innovation has been studied from many disciplinary approaches, including economics (Baptista 2000; Karshenas and Stoneman 1993; Reinganum 1981), sociology (Woolgar et al. 1998; Rogers 1995), marketing and management (Dos Santos and Peffers 1998; Hannan and McDowell 1984; Robertson et al. 1996), geography and organizational ecology (Ciciotti et al. 1990; Antonelli 1989; Benvignati 1982; Oakey 1984; Thwaites and Oakey 1985).

Distinctions can be made between:

- Technological and non-technological Innovation, and
- Product and process Innovation (OECD 1992, pp. 27–9).

**Technological versus Non-technological Innovation**

Some authors (Damanpour 1991; Rogers 1995; Van de Ven 1986) have provided very broad definitions, describing innovations as new ideas or behaviours. It is the *perception* of newness, by those involved, which is central to Rogers’ (1995, p. 11) definition of innovation. That is, an idea or item need not have scientific novelty to be regarded as an innovation (Schumpeter 1964, p. 59).

These definitions of innovation include both technological (products, services, processes) and non-technological innovations (organizational processes, administration systems) (Damanpour 1991, p. 556). For example, Schumpeter (1964, p. 59) describes five types of innovation:

1. Introduction of a new commodity
2. Introduction of a new production method
3. Opening up of a new market
4. Change in the source of supply
5. Re-organization of an industry.
The first two types are considered to be true technological innovation in the Schumpeterian sense, where technological innovations are new products and processes or significant changes of products and processes, and have an economic result. Thus, where improvements in quality and productivity outputs of a manufacturing process are required, the focus should be restricted to technological innovations.

**Product versus Process Innovations**

The OECD’s *Oslo Manual* (1992; 1997) separates innovations into two types: product and process innovations. A product innovation is ‘the commercialization of a technologically changed product’. Furthermore, a technologically changed product is one whose design is altered to provide new or improved performance over previous products. The product’s characteristics, attributes, and design properties may be significantly changed – a major or radical product innovation – or an existing product may have significant performance improvements – an incremental product innovation.

A process innovation, alternatively, is a ‘change in the technology of the production of an item [which] may involve new equipment, new management and organization methods, or both’ (OECD 1997, p. 10). A process innovation can occur in any way a product is produced. In addition, a product innovation by one organization may be adopted as a process innovation by another organization. Process innovations can thus enhance quality and productivity outputs, and therefore provide significant competitive advantages.

Product innovation can take two broad forms:

- Substantially new products: we call this ‘major product innovation’
- Performance improvements to existing products: we call this ‘incremental product innovation’ (OECD 1997, p. 29).

**Major product innovation**

This is a product whose intended use, performance characteristics, attributes, design properties or use of materials and components differs significantly compared with previously manufactured products. Such innovations can involve radically new technologies, or can be based on combining existing technologies in new uses.

**Incremental product innovation**

This is an existing product whose performance has been significantly enhanced or upgraded. This again can take two forms. A simple product may be improved (in terms of improved performance or lower cost) through
use of higher performance components or materials, or a complex product which consists of a number of integrated technical subsystems may be improved by partial changes to one of the subsystems.

In biotechnology and the pharmaceutical industry the approval of New Molecular Entities (NMEs) by the US Food and Drug Administration (FDA) are the most visible form of major product innovation. The FDA maintains its list of New Drug Approvals, however many of these approvals are for variants of existing drugs rather than entirely new drugs. Variants would be considered to be incremental product innovations. The FDA equivalent in Europe for drug approval is the European Medicines Evaluation Agency (EMEA).

As its name suggest the FDA is not concerned only with drugs. The products the FDA regulates include:

- Food – covering food-borne illness, nutrition, and dietary supplements
- Drugs – prescription, over-the-counter, generic drugs
- Medical devices – such as pacemakers, contact lenses, hearing aids
- Biologics – such as vaccines and blood products
- Animal feed and drugs – for livestock and pets
- Cosmetics – safety, labelling
- Radiation-emitting products – cell phones, lasers, microwaves
- Combination products – multi-category products which may include drugs and biologics as the move away from small molecule pharmaceuticals leads to more complex biologics in the drug development process.

Approval by the FDA does not assure success, nor does it assure safety, as has been recently demonstrated by Vioxx, the Merck product approved by the FDA in 1999 ‘for the reduction of signs and symptoms of osteoarthritis, as well as for acute pain in adults and for the treatment of primary dysmenorrhea’ (Statement of Sandra Kweder, Deputy Director, Office of New Drugs, FDA, before the Committee on Finance, 18 November 2004).

The product is believed responsible for many thousands of heart attacks due to increased cardiovascular risk from the drug, particularly in the older target group of patients. Merck’s share price plummeted over 25 per cent in one day on news of the withdrawal of Vioxx from the market due to side effects. However the FDA’s web site provides solid reasoning for permitting a drug to market which has some risks attached:

at the heart of all FDA’s medical product evaluation decisions is a judgment about whether a new product’s benefit to users outweighs its risks. No regulated product is totally risk free, so these judgments are important. The FDA will allow
a product to present more of a risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions (FDA Approvals for FDA-Regulated Products http://www.fda.gov/opacom/7approvl.html).

Of course this even displays the limits of the Schumpeterian concept of innovation. Vioxx reached the market; in fact it was very successful, having been approved in Europe, a number of countries in Asia, Australia, and New Zealand. It achieved commercialization and a high level of product diffusion through market up-take, no doubt assisted by Merck’s extensive market and distribution network. Yet in the long run it will be a failure, as it has not achieved what the company had hoped it would in terms of risk mitigation while offering positive clinical results, and its commercialization ceased from September 2004. The legal battles, class actions, loss of reputation and market capitalization, as well as the marketing effort required for revival will probably result in a net loss from this product for Merck and will have major impacts on the industry.

The FDA has already had its reputation as the lead regulatory body in the world tarnished with Vioxx, Celebrex and a spate of recent product market withdrawals and warnings. Other major bodies have tended to follow most regulatory approvals handed down by the FDA, its pre-eminence position being based on strong clinical trials and stringent approval processes, to the point that Phase IV clinical trials are about to become de rigueur in the industry. Any flaw in the process will have major implications for the industry and will be felt far and wide. This itself will have a major impact on future product innovations, as it is likely to slow the already slow approval process, require higher significance and efficacy levels and reduce the number of candidates reaching the market.

Expect to see more stringency, longer approval lead times, compulsory Phase IV trials, post-market testing dramatically increased, separation of roles within the major approval bodies, major marketing campaigns to restore confidence in the system and life generally becoming more difficult for NBFs with products in the pipeline. This will be a significant story of not only innovation, but of diffusion. Much will be learnt from this and much will change as a result.

**Process innovation**

Process innovation refers to the adoption of new or significantly improved production methods. These methods may involve changes in equipment or production organization or both. The methods may be intended to produce new or improved products, which cannot be produced using conventional plants or production methods, or essentially to increase the production efficiency of existing products.
Later innovation survey guides differed from the OECD guidelines in some respects. The OECD’s definition of innovation is restricted to technological innovation. The Australian Bureau of Statistics has widened this definition to include non-technological innovation. Non-technological innovation comprises three major aspects relating to the operation of a business rather than specifically to the products or services they produce. Figure 1.1 provides a summary of the major types of innovation referred to in this research study.

**WHAT IS TRADITIONAL ENTREPRENEURSHIP?**

The word ‘entrepreneur’ is derived from the French word ‘entreprendre’ meaning ‘to undertake’ (Ronstadt 1985, p. 28). The traditional entrepreneur is one who undertakes to control, coordinate and assume the risk of a business in a competitive marketplace. Today’s entrepreneurs possess those same features and have to be versatile in facing the challenges of a dynamic environment. Today’s entrepreneur is an innovator and developer of ideas; he or she seizes opportunities and converts them into marketable entities; at the same time they have to lead a team, seek out capital and resources while creating something unique and of value to others (Montagno et al. 1986).

Although no single definition exists, it is commonly agreed that the entrepreneur is an agent of change, especially in a growing world of free
enterprise and capitalism. In this sense, the traditional entrepreneur is the
greatest risk-taker but ultimately claims the greatest rewards. This enviable
nature of the entrepreneur spans every industry – there is one to be found
in manufacturing, services, technology, agriculture and so on.

**Entrepreneurship as Conceptual Orphan – Early Economic Writings**

While the role of entrepreneurs and entrepreneurship has never been denied,
its most debilitating facet is its limited, often cursory, coverage by the great
thinkers on economics and business. John Kenneth Galbraith’s eloquent
the mercantilists and their successors the entrepreneurs, being the nouveau
riche, were not favoured by economists who, like the artists of the time, were
patronized by the aristocracy and landed gentry, a class which felt threatened
by the emergence of the Industrial Revolution. As Galbraith muses ‘was the
Industrial Revolution the product of inspired entrepreneurship? Was it an
early step in a long process by which inventions, so far from being an inde-
pendent innovating force, are the predictable achievement of those who, with
brilliance and inspiration perceive the possibility of change’ (1987, p. 58).

The great debates have considered groups whose ranks would largely
consist of entrepreneurs; the mercantilists. Their identification often came
in a political context in which landed aristocracy’s pre-eminence was threat-
ened by this ‘new rich’ class. The response came in the form of the intel-
lectual elite in France at the time, the Physiocrats, led by Quesnay (1694–1774).
Through their ideal of the *Produit Net* in which nature, land and its groups
were considered the only source of wealth the Physiocrats sought to retain
the landed aristocracy’s rightful place at the head of the economic and social
order, and negate the role played by the mercantilists, the entrepreneurs.

Even Adam Smith, despite being appointed for some time as Com-
missioner for Customs in Edinburgh, was no friend to the mercantilist, the
merchant class. His distrust is evident in his passage, ‘people of the same
trade seldom meet together, even for merriment and diversion, but the con-
versation ends in a conspiracy against the public, or in some contrivance to
raise prices’ (Smith 1776 [1986]). The forerunner of the modern-day anti-
trust, anti-competitiveness laws can be seen in these lines. This is despite
strong belief that the greatest of all economic, and arguably social, steps
forward occurred as a result of a combination of entrepreneurship and
innovation.

It is not surprising then that the political agenda, which is always inex-
tricably linked to economic writings, did not favour a positive portrayal of
the role of the entrepreneur and of entrepreneurship. Where there is little
support, or in the case of the Physiocrats, of Marx and to a lesser extent of
Smith, there is downright disdain, and tomes on the virtues and necessities of such groups will be difficult to obtain, unless by one of their own. It is this lack of consideration throughout the development of economic thought and principles, which has likely been the greatest contributor to the lack of a disciplinary base that entrepreneurship has experienced. There is also the fact that the small businesses created by entrepreneurs constituted a maligned area of the microeconomy until works such as Birch’s (1979). Such events conspired to deny entrepreneurship its own lineage and body of works upon which to rely.

Thankfully for the discipline of entrepreneurship, the sentiment amongst great economic thinkers mellowed in the first half of the twentieth century. A better profile of an entrepreneur could not have been found than that envisaged by Weber as he explains what Schumpeter would probably refer to as creative destruction. Weber refers to the textile industry of the nineteenth century and its dramatic shift from the leisurely traditionalist business practice to that of entrepreneurial capitalism.

... Now at some time this leisureliness was suddenly destroyed, and often entirely without any essential change in the form of organisation, such as the transition to a unified factory, to mechanical weaving etc. What happened was, on the contrary, often no more than this: some young man from one of the putting-out families went out into the country, carefully chose weavers for his employ, greatly increased the vigour of his supervision of their work and thus turned them from peasants into labourers. On the other hand he would begin to change his marketing methods by so far as possible going directly to the final customer, would take the details into his own hands, would personally solicit customers, visiting them every year, and above all would adapt the quality of the product directly to their needs and wishes. (Weber 1930, p. 125)

If this is not a scenario of a small business entrepreneur undertaking extensive process innovation, then what is?

For John Maynard Keynes, the main emphasis of his major work *The General Theory of Employment, Interest and Money* (1935), was stated succinctly by himself: ‘The object of such a title is to contrast the character of my arguments and conclusions with those of the classical theory of [economics]’ (p. 3). As Keynes himself indicates, ‘The classical economists was a name invented by Marx to cover Ricardo and James Mill and their predecessors . . .’ (p. 3).

So Keynes’ emphasis was clearly upon developing a new economic thought for an era dominated by the Great Depression. Even with his eyes fixed squarely on economics Keynes in his General Theory still referred to entrepreneurs on numerous occasions, at times in some detail and usually in a favourable light. Just as Schumpeter believed unequivocally that
innovation was an economic concept, Keynes saw entrepreneurship clearly as an economic phenomenon. This is based upon Keynes’ distinction between speculation and enterprise. This distinction is underscored in Keynes’ look at future policy directions in his concluding notes as he writes:

Thus we might aim in practice at an increase in the volume of capital until it ceases to be scarce, so that the functionless investor will no longer receive a bonus; and at a scheme of direct taxation which allows the intelligence and determination and executive skill of the financier, the entrepreneur et hoc genus omne (who are certainly so fond of their craft that their labour could be obtained much cheaper than at present) to be harnessed to the service of the community on reasonable terms or reward. (1935, pp. 376–7)

We must accept that despite being written for a possibly different audience, and using some different terminology, many of the concepts that support our current research are available in the earlier writings, if we care to look. Further, as many of the writings contain anecdotal case studies, they are inherently flexible in their application.

Weber looks at entrepreneurship in his own current context and asks whether it differs from previous eras: ‘At present under our individualistic political, legal, and economic institutions, with the forms of organisations and general structure which are peculiar to our economic order, this spirit of entrepreneurship might be understandable’ (1930, p. 72). Is he writing in 1928 or 1998, without the reference the distinction is difficult to make?

Nevertheless those extolling the virtues of entrepreneurship remained limited in number and unsung in wider debates. Even in the post-war era other disciplines aligned with entrepreneurship, such as innovation, developed in leaps and bounds, assisted in no small part by the works of Joseph Schumpeter and other Austrian School economists such as Kirzner and Lachmann (though their disputes over the premise of equilibrium and disequilibrium remain, albeit posthumously). This impetus was added to by Rogers (1966), Abernathy and Utterback (1978), Tushman and Anderson (1986), and a succession of other subsequent writers. This provided the lineage, the chronology that all disciplines rely on in their necessity to establish their perceived centrality. The entrepreneurship lineage, the extant chronology of important major works is a relatively short one.

As a result, entrepreneurship has been bereft of dominant paradigms, it has hence had to borrow from other disciplines to build its theoretical depth and undertake its analyses. Major borrowed concepts upon which economic entrepreneurship has been based in recent years include

- Transaction cost economics (TCE)
- Resource-based view of the firm (RBV)
Institutional theory
Networks and alliances.

These concepts will be raised and explored throughout the ensuing chapters as their influence and value is undeniable in explaining entrepreneurial phenomena.

ENTREPRENEURSHIP AND INNOVATION

Post-Fordist or post-industrial influences (Keeble 1997) have created a less antagonistic, even supportive environment for high technology companies and entire industries to emerge and grow. Such influences include rapidly changing environments, moves away from mass production toward customization and mass-customization, the application of generic technology which advances communication and production processes, a declining emphasis on price competition and price competitiveness through volume output and economics of scale. The central theme of this development has been the appropriate application of technology through innovation, which itself is dependent upon the skills and risk taking of an entrepreneur. Put simplistically in Figure 1.2, the essential features have a strong causal relationship.

These post-industrial influences have created an environment conducive to the growth of high tech firms and entire industries. These influences include:

- Rapidly changing environments, particularly globalization impacts;
- A trend from mass production toward customization;
- The application of generic technology that advances communication and production processes;

![Figure 1.2](image-url)

*Figure 1.2 The relationship between factors in the improved standing of entrepreneurial businesses*
A declining emphasis on price competition and price competitiveness through volume output and economics of scale.

The central theme of this development has been the appropriate application of technology through innovation, which itself is dependent upon the skills and risk taking of an entrepreneur. Simplistically, the essential features of both entrepreneurship and innovation have a strong relationship; it is the causality that is debated.

In this situation, the fundamental role of innovation is to achieve profitability for the firm; it is a means to an end, not an end in itself. While for the individual firm the goal is profitability, the collective impact of this goal is economic change. Governments around the world therefore regard biotechnology as important since it has the potential to bring economic prosperity as well as ushering in a new economic order in the national/regional economy, creating a shift away from dependence on commodities and traditional industries for revenue.

The essential form of entrepreneurship is considered to be the ‘creation of new enterprise’. Therefore an ‘entrepreneur’ could be considered to be one who creates the new enterprise. It has also been identified that ‘entrepreneurship’ is a ‘process of becoming rather than a state of being’ (Mazzarol et al. 1999). This means that small businesses often commence as self-employed people or micro-businesses. If their existence is justified then they are provided the opportunity to grow and create employment for others. Innovation is an essential element of the entrepreneurial effort. Entrepreneurs must innovate in order to be successful. The form this innovation takes can vary according to the type of entrepreneur, the market and product requirements and the life cycle stage the business is currently experiencing. The type of entrepreneur is an important element in the success of a biotechnology company. Although there is no archetypical entrepreneur, there are certain recognizable characteristics of entrepreneurs that are worth noting.

There are three things that according to Schumpeter (1934, p. 89) make it easier to start a new enterprise:

- Offering goods and services that are new
- Some new enterprises use new methods of production or marketing or draw on new sources of materials or components to offer more cheaply or conveniently than competitors
- Some new enterprises are able to establish a new industry structure or exploit a new style of regulatory environment more effectively and/or rapidly than their rivals.
It is worth bearing in mind, the impact on the economy if, instead of the usual 10 to 15 per cent of small business owners being entrepreneurs, 90 per cent of them were.

There is also an important distinction to be made between the terms ‘innovation management’ and ‘entrepreneurship’. One is managing the research and particularly the development process, the other is a far more broad strategic approach to running a business.

Keynesian economic principles, as robust as they have been in the past, were written in an industrial era, in a time before technology changed the imperative from size and scale to flexibility. The sector of the economy to benefit the most from these revolutionary developments has been that sector which already possessed many of the features which would provide competitive advantages: flexibility, willingness to incorporate new approaches and technologies, low capital base, responsiveness to customer needs, i.e. small business.

There was one feature which was generally lacking in small businesses which in the Keynesian era had precluded them from competitiveness in many established industries and led them to be written off as anachronism by many of the great economic thinkers of history, such as Keynes himself, Schumpeter, Marx and Smith. They lacked knowledge of the market in which they operated. With small production runs, lacking in resources due to a low capital base, little market share and hence negligible market power, small firms found it difficult to access the necessary infrastructure they required for competitiveness. Competitiveness could only be obtained through reducing the cost of utilizing the available industrial infrastructure – namely roads, rail, ports and more recently airports, as well as the education system, most efficiently. The only way to achieve efficiency was through reducing the per-unit costs of transporting products to market. Hence the reliance on economies of scale. Those firms which had achieved economies of scale had access to the available infrastructure and therefore had an advantage over those that did not. Not surprisingly then small business was not competitive in markets which had become established and where size was the key to competitiveness.

With size, came access to not only the physical infrastructure but to other advantageous factors such as education, and information, each of which could be restricted under the traditional industrial infrastructure to those firms who had the means to access. This meant that market knowledge lay in the hands of large firms, thereby improving their ability to make decisions based upon reliable data.
Technology Development and Entrepreneurship and the Demise of Traditional Microeconomic Thinking

In the years since 1985 there has been an increasingly viable body of literature emerging which has supported the focus on small business as the engine room of economic activity in national economies. Much of this literature has unfortunately flown in the face of traditional economic principles and has therefore been severely critiqued as lacking theoretical underpinnings. The emergence of small business as a force within industrialized economies has coincided with the failure of Keynesian economic principles to be effectively implemented. This can largely be traced to the oil crisis of the early 1970s and to the accelerated development of technologies which improved the productivity of manufacturing and reduced the reliance upon traditional petroleum products.

This emerging technology has been significantly supported by corresponding developments in computerization and transistorization, initially specifically in the electronics-based industries and then diffusing to other related and then unrelated industries. The uptake of the technological advancements, particularly in manufacturing has meant that production costs have been dramatically reduced for many goods and indeed for services.

The impact of this burgeoning technology base has been twofold: It has led to the reduction in the costs of production and subsequently the price of products which come to market. This has meant that firms no longer need to rely upon as large a capital outlay as previously to achieve sufficient volume of production and therefore competitiveness in a market.

The reduction in the cost of production and the subsequent lowering of prices for products has meant that many products which were previously seen as luxury items have become more available to a larger proportion of the population. This has led to a reduced preference for mass produced products and an increase in the desire for customized items. Such a demand change has run counter to the traditional economies of scale requirement for competitiveness. Given the emerging technologies which are diffusing so rapidly as to impact on the majority of secondary and tertiary industries, the markets in which firms are operating are also changing rapidly. In parallel the technology itself allows for increased flexibility in the production process and an improved ability for those firms most willing to incorporate those technologies, the innovative firms, to meet the changes in demand rapidly. For instance retooling in many industries is not such a major or time and resource dependent task as previously. Hence the requirement for large production runs to reduce costs of production have been reduced. This again parallels the changing tastes and preferences of consumers toward customized over mass-produced products.
The consequence is that economies of scale no longer hold the key to competitive advantage as they previously did. Flexibility, in production and in meeting the rapidly changing demands of consumers is increasingly the order of the day.

In Chapter 2 a more thorough discussion of the emergence of entrepreneurship in the biotechnology context is presented. The generic material in this chapter, coupled with the biotechnology specific exploration of entrepreneurship in Chapter 2 will set the scene for the detailed analyses and discussions in the ensuing chapters.

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