Chapter 1

Introduction

The term "globalization" was coined by Theodore Levitt, in 1983 through an article he wrote in Harvard Business Review entitled "Globalization of Markets", which appeared in HBR in its May-June issue (Mullman, 2006). The literature, however, has tended to date the start of globalization to a much later date, relating it to the experience of the West. However, there is no agreement on when globalization actually originated (Guillén, 2001).

Globalization has been defined by many authors in a variety of ways due to the varied approaches their definitions are based upon, such as economical, political, financial, technological etc., One common thread that comes out of the various definitions that exist for globalization is that globalization is primarily an economic phenomenon, involving the increasing interaction or integration of national economic systems all over the world through growth in international trade, investment and capital flows.

According to Raskin (2002), the phenomenon of globalization is also associated with a rapid increase in cross-border social, cultural and technological exchange whereas Jones (1995) aptly suggests that globalization may simply be an intensification of the process of international interdependence. It is a function of the growth of competition in an international free trade system which is intensified by the diffusion of technology.

Globalization is characterized by the overlap of social, political and economic activities across continents and intensification of interconnectedness of trade and culture. This is leading to a situation wherein, distant, local events which can be highly significant elsewhere will have enormous global consequences. Due to this, the boundaries between domestic matters and global affairs are becoming increasingly blurred. A good example is the local US Subprime Crisis which is adversely affecting economies across the world.

According to Friedman (2006), globalization primarily brings about the following four types of changes:
• consolidation of social, political and economic activities across political frontiers, regions and continents.

• intensification, or the growing magnitude, of interconnectedness and flows of trade, investment, finance, migration, culture, etc.

• growing extensity and intensity of global interconnectedness can be linked to a speeding up of global interactions and processes, as the evolution of worldwide systems of transport and communication increases the velocity of the diffusion of ideas, goods, information, capital, and people.

• growing extensity, intensity and velocity of global interactions can be associated with their deepening impact such that the effects of distant events can be highly significant elsewhere and even the most local developments may come to have enormous global consequences. In this sense, the boundaries between domestic matters and global affairs can become increasingly blurred.

The following visual representation (Figure 1.1) depicts the various phases of change and their inter-relationships responsible for levelling the round world – leading to the phenomenon called “Globalization” – “Flatworldization”.

**Figure 1.1 - Leveling the round world flat**

In a nutshell globalization can be thought of as the widening, intensifying, speeding up, and growing impact of world-wide interconnectedness.

In the last decades science and technology have experienced an impressive advance. According to Hodgson (2003) this is inherent to capitalism. Competition pressures firms to pursue profits through two main means. Firstly, the conquest of new markets by geographical expansion and/or the introduction of new products, such as new technologies or skills. Secondly, by cutting costs through the adoption of new technologies and new skills. Hodgson also explains that "in this quest for innovation,
the frontiers of science and technology are advanced, leading to new fields of knowledge and enquiry" Hodgson (2003). Furthermore, he argues that because "services are generally more diverse than manufactured goods; diversity also increases with the increasing relative size of the service sector".

In Osterwald’s (2005) view, the link between information technology advancement and business models is particularly strong, since information technology advancement has been a strong enabler for a variety of innovative business models.

In summary, advances in information technology, specially internet technologies has contributed very significantly to enable worldwide real-time interconnectedness and these technology based innovations and advances have triggered the process of achieving competitive advantage by businesses across the globe, irrespective of the size, nature of business or the geographical location/s of these organizations.

By conceiving it in this way, it becomes possible to map empirically patterns of world-wide links and relations across all key domains of human activity, from military to the cultural. On mapping the world-wide patterns of this phenomenon it becomes evident that globalization has also brought about the following changes and advantages in some cases to businesses:

- global market for all products, leading to the creation of Global brands
- emergence of worldwide production markets and broader access to a range of goods for consumers and organizations
- global structures leading to greater and more efficient way of doing business
- development of a global telecommunications infrastructure and greater transborder data flow, using technologies such as the Internet, communication satellites, submarine fiber optic cable, and wireless telephones
- greater freedom of movement of goods, people, services and capital
- economical offshore production
- virtual real time communication
- standardization of logistics
- new technology niches etc.,

What can be distilled from the above is that the reality “Globalization forces everyone to compete with the cheapest producers” is brought into stark focus (Friedman, 2006).
To a business leader, this means that there are more challenges than ever from stakeholders such as competitors, customers, investors and regulators. The business also needs to survive, grow revenues, become more agile in the face of competitive and market pressures and provide customers with optimum service. One of the best ways to achieve this is through globalization of the organization. Achieving globalization at the organizational level would bring in widening, intensifying, speeding up, and growing impact of world-wide interconnectedness which can be used as a competitive advantage. Successful businesses are responding to this phenomenon of “global competitiveness” by optimizing their “business services” through outsourcing and hence attain a differentiation leading to a competitive advantage, from the business perspective.

Globalization for a business from the organizational context can be achieved through either outsourcing or through offshoring its business processes. Outsourcing can in turn be defined as an organizational practice to purchase goods from or to subcontract services to an outside supplier. On the other hand, Offshoring can be defined as a practice of moving business processes or services to overseas locations or vendors so as to reduce costs. Even though international trade economists have turned their attention to fragmentation/outsourcing only recently, the phenomenon, and terms to describe it, is not new. Landes (1998) traced the origin of outsourcing to 13th century Europe. It stemmed from attempts to reduce guild controls in the cities, and use abundant and cheap female and child labour force available in the countryside to produce finished yarn.

Outsourcing, primarily involves transferring ownership of an organization’s business activities to a service provider. For a fee, the outside service provider carries out the activities and maintains responsibility for their outcomes (Chamberland, 2003). It has come into prominence only after the change management approaches of the past two decades have largely been exploited. Cost reduction and competitive positioning in the 1980s, process improvement and re-engineering in the early 1990s and enterprise resource planning, customer relationship management and web technologies of the late 1990s have all but run their course. To create value for a business in today’s markets means transforming the organization into a focused, responsive, variable and
resilient business and can primarily be achieved through the Business Process Outsourcing (BPO) Model.

In a BPO relationship, some or all business processes which are normally not critical to the organization and do not form the “Core Competency” for the organization are outsourced to an external partner. The external partner in turn would own these processes, deliver services at agreed upon levels and add value by improving the process. At the end of the contract the external vendor would – if previously agreed upon transfer the improved process back to the customer.

In this study, the focus is only on outsourcing of business processes leading to optimization in the Life Sciences industry. The term Life Sciences includes the biomedical, biotechnology, medical devices and the medical diagnostic industries. The generic model framework being evolved in this study creates and implements an effective model that predicts the essential, elemental critical success factors and their relationships which affect business performance of organizations in the Life Sciences BPO Industry.

1.1. Life Sciences Industry characteristics and trends

In this research study when we refer to Life Sciences industry we focus our attention primarily to the biomedical industry which is in the business of discovering and developing medical solutions, products, procedures etc., to treat unmet medical needs. Although the study encompasses both, business process outsourcing customers and service providers to this industry segment, the outcome of this study can be applied to any industry with similar characteristics.

The biomedical industry develops innovative products for the prevention, treatment, and cure of human diseases. The industry is composed of four primary segments:

- Pharmaceutical segment: which is the industry’s mainstay and is composed of large, fully integrated, global players.
- Biotechnology segment: which is a comparative upstart, having emerged commercially only 30 years ago, but it is increasingly the engine of innovation in biomedicine.
• Medical device segment: which is much older than biotech, but is composed of fewer players, and owing to the nature of its products, exemplifies the life-saving power of “convergence”: a marriage of engineering know-how and biomedical science.

• Diagnostics segment: which has grown up along mainstream pharmaceuticals, and has acquired a new dynamism and centrality since the advent of the genomics revolution.

These segments were long regarded separate and distinct, but in the 21st Century these should be considered as fundamentally convergent and increasingly interrelated so to ensure there is a more integrated approach to treat a disease or an unmet medical need. A spate of recent mergers, acquisitions, partnerships happening around the globe between diagnostics, medical device, biotechnology and pharmaceutical organizations in this sphere, indicates that the convergence model has been initiated and is under progress.

This industry invents products that people need to avoid illness, maintain their health and save lives. The importance of its products for individual and public health sets up high expectations for performance and commitment. Hence it is essential that the industry fulfils its commitment by providing safe and effective medicine on time.

Although a recent study shows that most consumers believe prescription drugs have a positive impact on people’s lives (DiMasi, 2001) the positive impact occurs only when new medicines satisfy rigorous safety standards, provide new hopes and good outcomes, offer good value and are widely accessible to patients.

According to Lößfler (2006) the biomedical industry is made up of large, fully integrated, global players who have built competencies – right from discovering a drug to marketing the product globally. It experiences explosive growth in markets for the treatment of both chronic and acute illnesses where these markets are driven by a confluence of political and demographic trends – most notably globalization and population growth and aging -- as well as by new products resulting from the genomic discoveries of the late 1990s and early 2000s and a generally favourable policy environment.
The biomedical industry is characterized by some fundamentally unique forces due to the nature and end use of products it manufactures. Certain characters which are unique to this industry as listed under Figure 1.2 given below.

**Figure 1.2 - Biomedical Industry Characteristics**

<table>
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<th>• Driven by science.</th>
<th>• Requires specialized human capital.</th>
<th>• Very high science risk.</th>
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<td>• Formidable regulatory oversight.</td>
<td>• Exposed to a wide range of ethical and political issues.</td>
<td>• Constant innovation and discoveries very essential.</td>
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<td>• Needs to constantly generate and adapt new technologies especially in drug discovery.</td>
<td>• Market demand is disease driven and cannot be influenced.</td>
<td>• The commercialization process is distinctive across the industry.</td>
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<td>• Intellectual property right protection defines revenue life cycle of products and hence key for growth.</td>
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The global biomedical market was reported to be about US $643 billion in 2006 (IMS, 2007). The US, Europe and Japan account for 77% of the market although they account for less than 15% of the global population (Scheffler and Pathania, 2005). Among the developed countries, the US dominates, it accounts for 38% of all global spending. The US market is huge and very important not just because it is the most populous of developed countries but due to a relative absence of price controls. The unit realizations of biomedical companies are higher in the US.

For biomedical organizations, the challenge lies in shaping their business strategy and their competitive landscape in terms of profits, costs, and above all ethics. With significant technological advances in the drug discovery process and the development of the biotechnology industry, biomedical organizations are facing increased pressure to produce more and better drugs, at a faster rate and with greater economic benefits to the business. Hence, unlike most other sectors the biomedical industry focuses on and allocates the majority of its resources to the process of drug discovery and development, whilst processes such as manufacturing, marketing, and logistics are very much secondary (Halliday et al., 1997).
The R&D process is a long and uncertain road from the laboratory to the marketplace. Only 1 in 5000 promising molecules makes it to the product stage. On average, cost of developing each new medicine costs US$800 million in R&D costs (US Department of Health; 2006) and takes almost 10-15 years on average to get through all the stages of development (US Department of Health, 2005). Estimated total biomedical R&D expenditures in 2005 was around $51.3 billion (Pharmaceutical Research and Manufacturers of America (PhRMA), 2006).

A study by CMR International and Accenture clearly articulates that to consistently deliver one submission of a new medicine to the US FDA (the regulatory agency which reviews information submitted by biomedical companies and then authorises marketing of the medicine in the US), a biomedical company focusing exclusively on new targets, should initiate 90 new projects, considering a 10 percent success rate and an existing total discovery portfolio of approximately 200 projects.

Coupled with this inherent pressure on the industry’s business model, the factors indicated below, have created a challenging environment to the industry, which, after decades of exceptional growth is going through a period of slow earnings expansion. These diminished returns show-up clearly in the stock market where biomedical companies’ valuations are at a high time low.

- Declining worldwide margins for biomedical industry when EBIT% is considered is very visible. (EBIT: Earnings before interest, taxes, weighted average of top 10 companies by margin for which data was available) (Bloomberg).
- Faltering sales and marketing campaigns associated with high costs of administrative overheads (market valuation implies only a 4% growth in sales rate) (Economist, 2005).
- A continuing trend is declining drug development productivity (higher costs, fewer medicines) affecting portfolio management and lifecycle management reflected by the trend of having no new launches from 33% of the 16 top Pharma companies in 2003. Both in Europe and in the US only 12 products were launched by the top 16 companies in 2003. This compares with 16 and 15 in Europe and the US respectively in 2002.
- Declining global biomedical sales on a year on year basis, compared to 14.50% in 1999 to around 7.0% in 2006. (Source: IMS Health Market
Prognosis (includes IMS Audited and Unaudited Markets); All information current as of March 2, 2007).

- The number of drug development projects initiated has been stable since the 1990s despite an increase in spending; success rates in each phase of development have declined; and the phases of development have taken longer to complete. There are many reasons for this, including increased regulatory scrutiny, the current focus on chronic diseases, the inflation of development costs, increased focus on product safety and more aggressive patent challenges, which can make it difficult to focus on new indications.


- Loss of public trust due to safety issues leading to withdrawal of marketed products (E.g.: Merck’s Vioxx) (Economist, 2005)

- The primary theme for the Big Pharma peer set is the continued onslaught of generics, eroding the sales of small molecule CNS and cardiovascular blockbusters (Datamonitor, 2006), leading to increased competition from generic (me-too) and biological medicines. For e.g.: the U.S. prescription generic drug market is projected to grow from an estimated $11.1 billion in 2001 to more than $19 billion in 2006, representing an average annual growth rate (AAGR) of 11.4%.

- Pricing pressures due to rigid pricing and reimbursement systems in Europe, parallel trade, re-importation, re-categorization – OTC, generic substitution, reference pricing etc., Cambridge (2003) estimates US re-importation of prescription biomedicals from Canada was equivalent to US$1.1 billion or approximately 0.5% of total US sales. Growth was up 134% in 2003 compared to 2002.

- Pricing pressure in the US, to get products approved and reimbursed by third party payers.

- Long development times, a lack of coordination within the company, not enough insight into customers, and a risk-averse corporate culture associated with limited application of the principles of strategic management to drug discovery.
The biomedical industry not seeking innovative ways to reduce their overall cost structure, while delivering a broader range of products and services to customers with increasingly shorter lifecycles – as being demanded by the market.

Globalization, organizational issues (such as metrics and measurement, structure, and people), and leadership remain three of the biggest challenges facing companies that are seeking to become more innovative.

Socio-political sensitivity around equal market access for all citizens, particularly to critical life-saving medicines, could become a major public affairs issue for the industry.

Faced with failing growth, the Pharma industry is pursuing options like M&A with other Pharma companies, biotech, Mid Pharma and/or generics manufacturers and acquisitional moves outside of 'Pharma space' to increase presence in medical devices, diagnostics and consumer healthcare. (Datamonitor, 2006). This movement would typically bring-in its own set of problem and ultimately not help put its house in order.

Barbhaya (2005) indicates ever increasing timelines for drug development and a flat R & D productivity judging by the numbers of Investigational New Drug Applications (for approval to test a new drug in man for the first time – to demonstrate the product is safe and effective when used) and New Drug Applications (for approval to commercially market the new medicinal product) filed in the last 15 years – even with an exponential increase in R & D budgets. He also states that Pharma R & D failure is a norm since it’s associated with a cumulative program success rate of just 1.5%.

In summary, he states that existing data indicates a fivefold increase in R & D spending with a modest increase in Investigational New Drug submissions and essentially a flattening of new drugs (new chemical entities) approvals for commercial use.

The researcher’s own study using data provided under Thomson Reuters “IDRAC” (a source of trusted global regulatory intelligence) database also confirms the approval rate statements given above. The approval trend of New Molecular Entities (NME) versus Biological Entities (BLA – biologic license approvals) is presented in Figure 1.3 given below. On an average, the linear graph would remain flat.
From the above factors it becomes evident that over the past decade, biomedical and life sciences companies have entered a difficult period where shareholders, the market and regulators have all created significant pressures for change within the industry. From thinning product pipelines and skyrocketing operating costs to calls for lower prices and a greater regulatory burden, the industry is confronting unprecedented challenges that are expected to radically transform the business.

In an atmosphere of declining research and development (R&D) productivity, mounting pricing pressure and changing regulatory requirements, global biomedical and life sciences companies face increasing challenges to achieve and maintain profitable growth, (PwC, 2006). Global biomedical business process outsourcing offers life sciences organizations an opportunity to overcome these challenges. By forming strategic relationships with outsourcing partners, companies can optimise their business services supply chain by inculcating delivery system innovation, focus on core competencies, progressing up the value chain, access specialized expertise, achieve cost-saving benefits and reduce burn rates that lead directly to greater shareholder value (by creating differentiation and hence competitiveness).

1.2. Motivation for this Research

Although global biomedical business process outsourcing seems to offer life sciences organizations an opportunity to overcome its inherent problems or challenges,
understanding the elements and organization structures which control and hence influence the final outcome of this process become very critical. In other words, understanding the elements of the business process outsourcing (BPO) business model, their influences and their relationships can help us predict the effect of the business models on the organization’s business performance.

Even though the concept of business model is potentially relevant to all firms, a search of the organization, economic, and strategy literatures, resulted in finding a few articles on the subject, and just one largescale empirical study (Amit and Zott, 2001). Although several authors have provided useful frameworks for analyzing businesses, such as profit models (Slywotzky, et al. 1997) and strategy maps (Kaplan and Norton, 2004) these approaches are based on a tradition of classifying firms into “internally consistent sets of firms” referred to as strategic groups or configurations (Cool and Schendel, 1987). These groups—typically conceived and organized through the use of typologies and taxonomies (Miles and Snow, 1978) were often used to explore the determinants of performance. None of these authors provided any insight on the biomedical outsourcing elements, typologies, taxonomies and their effects on business performance/success.

It thus becomes evident that few concepts in business today are as widely discussed—and as seldom systematically studied—as business models. Many people attribute the success of firms like eBay, Dell, and Amazon, for example, to the ways they used new technologies—not just to make their operations more efficient—but to create new business models altogether (Gurley, 2001). In spite of all the discussion about business models, however, there have been very few large-scale systematic empirical studies of them. This is especially so in the area of understanding the effect of business models on business performance/success in the Indian Life Sciences BPO industry. We do not know, for instance, how common different kinds of business models are in the economy and whether some business models have better financial performance than others.

This brief summary of related literature has motivated this research and this study provides a first attempt to answer these basic questions about business models and their effect on business performance/success in the Indian Life Sciences BPO industry. The research provides a theory-grounded proposal for understanding the effect of business models on business performance/success primarily through an
empirical approach. Specifically, the researcher is interested in the primary question of whether business models have performance implications.

1.3. Dissertation Organization

Chapter 2 examines prior literature with respect to elements, constructs, relationships of business models and its effect on business performance. In addition, it also includes description on topics which were used in carrying out specific pilot studies related to this research. This chapter includes the selection of a single business performance metric used in this study.

Chapter 3 describes research methodology used in this study. It also includes the study approach of this research. It also explains development of the survey instrument including content validity assessment and reliability analysis of the survey instrument.

Chapter 4 explains different tests applied to the survey data, presentation of results and interpretation of the test results. It also presents the results of hypothesis testing and comparative analysis. It also provides discussion of the result findings of the study.

Chapter 5 presents conclusion of this research including construction of the generic business model framework, the limitations of the study and contributions of this research, the limitations of the study and application of the findings to entrepreneurship and strategic management research, practical implication for managers and Future research.