



Diffusing knowledge-based core competencies for leveraging innovation strategies: Modelling outsourcing to knowledge process organizations (KPOs) in pharmaceutical networks

Samir Gupta ^{a,*}, Arch Woodside ^{b,1}, Chris Dubelaar ^{a,2}, Don Bradmore ^c

^a Department of Marketing, Monash University, Chisholm Tower, 26 Sir John Monash Drive, Caulfield East, Melbourne, Victoria, 3145, Australia

^b Boston College, Carroll School of Management, Department of Marketing, 450 Fulton Hal, 140 Commonwealth Avenue, Chestnut Hill, MA, 02467-3808, USA

^c RMIT University, School of Management, GPO Box 2476V, Melbourne, Victoria, 3001, Australia

ARTICLE INFO

Available online 21 January 2009

Keywords:
Networks
Pharmaceutical
Industry
Knowledge
Outsourcing

ABSTRACT

As pharmaceutical firms try to market their products and reduce costs, vertically integrated structures hamper innovation processes. Yet, pharmaceutical firms must innovate to compete. Outsourcing knowledge intensive activities to knowledge process organizations (KPOs) serves to reduce innovation process obstacles. Grounded in diffusion theory and strategic management literature, this conceptual paper explores four interrelated strategic concepts: core competencies, economies of scale and scope, knowledge sharing, and learning. This paper claims that (a) accumulated core competencies of multinational pharmaceutical companies (MPCs) erode over time and these companies become dependent on KPOs (b) MPCs must understand how KPOs manage core competencies (c) economies of scope benefit KPOs enabling them to sustain competitive advantages for their MPC partners, meanwhile the benefits from economies of both scale and scope shift from MPCs to KPOs (d) KPOs need to monitor their rate of learning to remain competitive. The paper identifies implications for industrial managers and directions for future research.

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1. Introduction

In order to be competitive, firms operate in knowledge networks. This paper investigates the relationships between network members, their performance outcomes, their interdependencies, and the way in which they share knowledge when conducting non-core critical activities (Powell, Koput, Smith-Doerr, 1996; Quinn, 1999, 2000). In particular, the paper focuses on these phenomena in the context of pharmaceutical firms and their use of knowledge process outsourcing (KPO) firms – defined as companies that have contractual arrangements to provide knowledge-intensive critical activities like research and development (R&D) to entities which would otherwise have completed them in-house (Aggrawal, 2007). KPO involves processes that demand advance information search, analytical interpretation, and technical skills as well as some judgement and decision making (Nair, 2006). For example, KPO functions are intellectual property or patent research, R&D in pharmaceuticals and biotechnology, data

mining, database creation, and a range of services such as biostatistical analysis (Nair, 2006).

In pursuing improved performance through knowledge sharing, pharmaceutical firms must face trade offs. These trade offs are between the immediate benefits of outsourcing the tedious development processes to focus on their core competency of research and the longer term risks associated with dependence on outside firms.

Multinational pharmaceutical companies (MPCs) like Pfizer sometimes outsource their non-core activity to KPOs. Building strong relationships with foreign companies (outsourced firms or KPOs) provides established firms (MPCs) with opportunities to learn about the activities of foreign firms (Karlsen, Silseth, Benito, & Welch, 2003). However, Karlsen et al. (2003) state that in order to get a better understanding, research ought to focus on activities (such as knowledge sharing) and how these activities contribute by leveraging knowledge-based core competencies.

This paper identifies the core competencies of the outsourced firm, showing how these firms reduce costs through scale and scope economies, share knowledge, and become efficient through learning in collaboration. Powell et al. (1996) suggest that more work is needed to fully understand why some collaborations lead to benefits for both the supplier and the buyer while other collaborations do not. Larson (1992) states that the use of network exchange structures represents a critical leveraging opportunity whereby resources can

* Corresponding author. Tel.: +61 3 9903 2492; fax: +61 3 9903 2900.

E-mail addresses: Samir.gupta@buseco.monash.edu.au (S. Gupta), woodsjar@bc.edu (A. Woodside), Chris_Dubelaar@bond.edu.au (C. Dubelaar), don.bradmore@rmit.edu.au (D. Bradmore).

¹ Tel./fax: +1 617 522 3069/6677.

² Present address: School of Business, Bond University, Gold Coast, QLD 4218. Tel.: +61 7 5595 1185; fax: +61 3 9903 2900.

gain competitive advantage without incurring capital investments by MPCs. One can argue that these non-core critical activities carried out by KPOs may prove to be a critical leveraging opportunity for suppliers in networks.

However, knowledge about how outsourced organizations benefit strategically is limited (Karlsen et al., 2003). Scholars address real-world problems that lack theoretical specifications and attempt to find practical solutions, as in the case of the biotechnology industry (e.g., Nohria and Eccles, 1992). Powell and Brantley (1992) argue that new kinds of organizational arrangements that have proliferated in the industry have been a response to competence-destroying breakthroughs. These authors ask the question: “Will the novelty fade ... [or will the outsourced firms] evolve into mature corporations and incumbent pharmaceutical and chemical corporations regain their former dominance?”

Core competence is the knowledge set that distinguishes a firm and provides a competitive advantage over others (Leonard-Barton, 1992). Leonard-Barton (1992) identifies four dimensions of knowledge. They include employee knowledge and skill, technical systems, managerial systems, and values and norms. The present article extends these dimensions and identifies four interrelated constructs when it comes to outsourcing non-core yet essential services in networks: core competencies; economies of scale and scope; knowledge accumulation, and learning, over time. In so doing, the aim is to understand the activities from a KPO perspective by investigating (a) how core competencies impact on KPOs over time (b) the impact of scale and scope economies over time and (c) how knowledge sharing and learning benefit KPOs over time. Within the pharmaceutical industry, clinical research Organizations (CRO) are their KPOs. To be consistent with pharmaceutical industry usage, we will therefore use the term CRO from this point forward in the paper.

The paper proceeds as follows. First, we provide background to the problem, we then show the significance of CROs in developing countries, followed by the conceptual framework, illustrated with case examples drawn from the pharmaceutical industry. We conclude with a discussion of future research directions and implications for industry.

2. Industry background

2.1. Innovation-related ailments in the pharmaceutical industry

The problem with pharmaceutical firms like Pfizer is that they are vertically integrated. *The Economist* (January 27, 2007) reports that, as profits gets squeezed by new generic drug manufacturing firms, finding new treatments becomes increasingly expensive and difficult for industry incumbents. Firms in this industry find themselves in a marketing and sales trap. They try to compensate by diverting resources from research to marketing. Industry consultant Roger Longman (*The Economist* January 27, 2007) of Windhover Information insists that firms like Pfizer need to move away from vertical integration towards horizontal integration. Outsourcing non-core, yet essential, activities including R&D activities and sharing of knowledge with outsourced firms may reduce lead times and cost in bringing new products to market. Wong et al. (2006) believe that the biopharmaceutical industry has recognized that a key challenge is to improve research and development (R&D) productivity. Arguing that the R&D environment is complex, these authors suggest that such R&D activities could be outsourced to developing nations like India and China, countries with world-class skills in chemistry, information technology, and a large pool of treatment-naïve patients.

The academic and business literature claims that large multinationals gain from focusing on core competencies (essential needs), reducing operating costs, freeing resources, and gaining access to world class capabilities (Namasivayam, 2004) in order to get to market quickly. However, how smaller firms can leverage their knowledge

and be competitive in dynamic network markets has had limited exposure in academic literature. Ravishankar and Pan (2008) suggest investigating the strategies employed by client organizations (i.e. clients of multinational firms) to develop a better understanding of how these network partners operate.

Achrol and Kotler (1999) propose that as firms move towards horizontal integration, they avoid long-term commitments, preferring to outsource their activities with multiple suppliers that compete for their business. However, Achrol and Kotler (1999) offer no empirical evidence to suggest the type of actions networked organizations may provide.

Substantial literature is available on the application and direction of marketing strategy. Varadarajan and Jayachandran (1999) identify seven key research concentrations, two of which are innovation and strategic alliances. Scholars call for future research in specific areas focusing, inter alia, on empirical generalizations, international orientation, and cooperative strategies with a micro-level analysis of firm behaviour (Calantone, Cavusgil, & Zhao 2002; Varadarajan & Jayachandran, 1999). Using a longitudinal case study approach, Narayandas and Rangan (2004) examine the evolution of three buyer–seller relationships that build and nurture long-term relationships in industrial markets. In their empirical study, Powell et al. (1996) suggest that firms in a wide range of industries are executing nearly every step in the production process through some form of external collaboration. They argue that biotechnology firms are opting to sustain the competitive ability to learn via interdependence rather than through independence by means of vertical integration. Powell et al. (1996) argue that biotechnology represents a competence-destroying innovation (cf. Schumpeter, 1932; Tushman and Nadler, 1986) because it builds on a scientific basis (immunology and molecular biology) that differs significantly from the knowledge base (organic chemistry) in the established pharmaceutical industry.

Unlike business process outsourcing (BPO), CROs provide domain-based process activities and expertise. They add value to the process by informing clients (based on data analysis and expertise) rather than just undertaking process activities. These firms carry out highly complex and customized processes that demand advanced analytical and technical skills as well as decisive judgements (Aggrawal, 2007). Aggrawal (2007) claims that the most important distinction between CROs and BPOs is that the clients (multinationals) are involved during the entire execution process and CRO services are part of that value chain. For example, in the pharmaceutical industry, an MPC may develop a drug which is then sent to a CRO for clinical trials based on an agreed protocol. Industries such as energy, banking, semiconductors, biotechnology, and insurance operate in this way (Quinn, 2000). Quinn (2000) claims that these types of industries frequently form temporary alliances to conduct highly complex and customized processes. These customized processes may involve biostatistical analysis, clinical data mining, clinical trial and analysis, joint research, complex investigation requiring high-level creative skills, and interactions amongst different specialized operations (Quinn, 2000).

The research reported here aims to understand how collaborative activities, such as advanced analytical and technical skills, lead to future opportunities for CROs. The concept of CROs is not new. However, in developing countries the concept of offering clinical trial services is just beginning and, as such, the development of theory in these evolutionary stages is important (Woodside, Gupta & Cadeaux, 2004). These new service providers are flexible and competent, enabling MPCs to allocate resources to innovation while delegating non-core activities such as conducting trials to CROs (Allen & Chandrashekar, 2000). Allen and Chandrashekar (2000) argue that outsourcing activities have moved beyond manufacturers outsourcing customer support or airlines and hotels outsourcing reservation services or IT services, for example, and into knowledge-intensive services like research and development.

2.2. India a hot bed for clinical trial activities for MPCs

The Boston Consulting Group (BCG) describes how India is home to a large pool of western trained, English-speaking scientists and managers (Wong et al., 2006). This combination creates a business environment rich in enthusiasm and support in global market processes, ethical standards, and technical demands. India has world-class skills in chemistry and information technology, and has a large pool of treatment-naïve patients, that is, those who have not taken any other medicine. Global consulting firm McKinsey (Iype, 2004) estimates that by 2010 there will be 700,000 speciality hospital beds and 221 medical colleges in India. It is estimated that 30% of clinical trials are conducted in private hospitals. Modern infrastructure in technology and transportation ensures speedy flow of clinical information and medical samples in appropriate refrigerated containers between hospitals and clinical trial centres. Furthermore, as India has diseases of both the tropical and developed world, pharmaceutical firms can use India as a hot bed to conduct non-core clinical trial activities on a broad spectrum of drugs.

In early 2005, with pressure from the international community mounting and the World Trade Organization threatening sanctions, India finally instituted a new regime of product patents. According to Wong et al. (2006), changes afforded to MPCs gave them the same intellectual property rights in India that they enjoy elsewhere by extending patent protection beyond manufacturing processes to the drug molecules. Meanwhile, government regulations are keeping abreast of latest developments and have removed much of the red tape that hindered effective ethics approval and patent laws. Wong et al. (2006) claim that the very same MPCs that once denounced Indian pharmaceutical firms are now partnering and entrusting them with vital research and development. This strategic shift puts the focus on CROs. From a managerial perspective, understanding their (CRO's) *core competencies, economics of scale and scope, knowledge sharing and learning* will fill an important gap in the strategic and industrial management literature.

The conceptual framework is developed by first examining the notion of outsourcing (resulting in Proposition 1 – P₁), then by drilling into network theory to examine how core competencies are managed (resulting in Proposition 2 – P₂), followed by an examination of the effects of prolonged knowledge and process sharing and the resultant transfer of advantages from the MPC to the CRO (resulting in Proposition 3). Finally we extend the investigation to the effects of learning strategies on the balance between the MPC and the CRO (resulting in Propositions 4, 5, and 6 – P₄, P₅, and P₆).

3. Conceptual framework

3.1. Outsourcing non-core yet essential services

Scholarly contributions to network theory in marketing (Achrol, 1991; Achrol, Reve, and Stern 1983; Anderson, Hakansson, and Johanson 1994; Webster 1992) and strategic management (Gulati 1995; Gulati Nohria & Zaheer, 2000) have dominated industrial marketing management of late. As competition intensity grows in industrial markets, firms battle for survival by developing networks, and seek marketing opportunities in new markets with new products in collaboration with partners (Achrol & Kotler, 1999; Kotler 2003). These networks have risen to prominence due to industrial restructuring, new players in the market, downsizing, and business process outsourcing in order to gain a competitive advantage over similar firms (Achrol, 1997).

A growing body of research is coming to terms with the economic impact of outsourcing. This research extends prior studies by including opportunities in outsourcing (Baxendale, 2004), the impact of outsourcing to developing countries (Bettis, Bradley & Hamel, 1992; Weidenbaum, 2005), from a strategic perspective (Moran, 1997;

Quinn, 1985, 2000), and the shift required in the mindset of managers when outsourcing services amongst interfirm partners (Allen & Chandrashekar, 2000). Researchers have examined interfirm relationships from a variety of theoretical perspectives, levels of analysis, and outcomes (e.g. Gulati et al., 2000). Gulati et al. (2000) propose that industry participants can be seen as part of the network of skilled resources and, where information is shared between organizations, can be a source of both opportunity and constraint. Magnani (2006) argues that technological diffusion facilitates outsourcing as it reduces the specificity of internal skills and knowledge and encourages convergence of core competencies over time.

Empirical studies suggest that an increasing number of pharmaceutical firms are outsourcing essential services such as biostatistical analysis (Mehta & Peters, 2007). Biostatistical analysis activities are high risk, and projects can fail at many different stages. Mehta and Peters (2007) argue that multinational firms that outsource biostatistics risk losing opportunities to improve innovations.

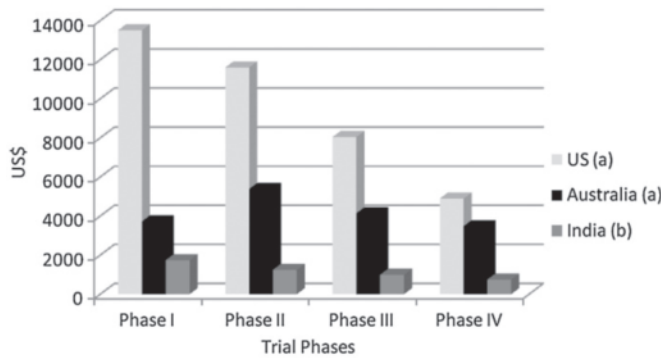
Biostatistical analysis is a non-core yet essential service that can be provided by a CRO. Thus, skill in biostatistical analysis can be a core competency of the CRO that is recognized as unique in the clinical trial process to establish efficacy, conform to regulatory requirements for marketing approval, manufacture in large quantities, and market and distribute the final product (Mehta & Peters, 2007). In the context of marketing, the role performed by biostatisticians is critical to the success or failure of clinical trials, with results of complex statistical analysis holding the key to regulatory approval to go to market. A growing body of business literature in the pharmaceutical industry claims there is a rapid escalation of outsourcing of processes such as biostatistics, and many benefits in sharing R&D in networks (Lerner, 1997; Wong et al., 2006). The problem with this body of research is that it focuses on the strategic benefits for the MPC that is outsourcing and not on the CROs to which the services are outsourced. The outsourcing of clinical trial services is a growing billion dollar business. This paper focuses on the strategic activities of CRO firms (cf. Quinn, 2000).

Over time, core competencies of manufacturing firms may erode as they become dependent on CROs, for the development of the final product. The proposition is stated as follows:

P1. *Core competencies erode over time as MPCs become dependent on the contribution made by CROs.*

Comment: Over time, core competencies of CROs (e.g. biostatistical services) grow and, as CROs become more proficient, MPCs become dependent on them. Furthermore, these value-added service functions are product and customer specific and MPCs will be dependent on CROs in getting approval to get new drugs to market. This frees up scarce resources that can be allocated towards innovation for new drugs to maintain the flow of discoveries. This triggers new core competencies for MPCs.

Case illustration: Industry experts claim that the global clinical trial industry is currently estimated at approximately US\$10 billion and has increased by almost 15% in the last year (Newton, 2007). Using this as a base and 15% compounded, the revenue from global clinical trials will generate US\$17 billion by 2010. In contrast, India expects to capture US\$2 billion by 2010 i.e. approximately 11% of the global clinical trial revenue. Other industry analysts (McKinsey & Co.) argue that the revenue from clinical trials will bring in only US\$1.5 billion to India (Iype, 2004). Although these reports are conflicting, what analysts do agree on is that the revenue from clinical trials will have a profound impact on Indian CROs. However, on innovation, Dr. Vasella, (CEO, Novartis) claims that “individual firms may rise and fall, but I believe the innovative power of the sector remains strong.” In contrast to the funds required for innovation, the cost of conducting various types of clinical trials (e.g. Phase I to Phase IV) when compared between developed and a developing country indicates a large difference, as shown in Fig. 1.



Source: (a) Woolley, K., and Woolley (2003) Clinical trials in Australia: Finding out the FACTS, *Good Clinical Practice Journal* 10(5). (b) Lambda Therapeutic Research Ltd (2008)

Fig. 1. Comparative clinical trial costs.

Clinical trial services that CROs provide have four phases. Phase I trials are conducted on a small number of healthy individuals to determine a drug's behavioral characteristics, such as safety at different dosage levels. These trials are used in particular to determine the pharmacokinetic properties (metabolism, absorption, elimination, and preferred method of administration) of new drugs. Phase II trials are the first test of the efficacy and safety of a drug on a limited number of diseased patients (between 50 and 300). During Phase II, characterization studies from Phase I are continued and completed. Phase III trials serve as proof of efficacy and safety of a drug. Hundreds to thousands of patients are involved and treatment is administered under real-world conditions. Finally, Phase IV trials are clinical tests (after a drug receives approval) that indicate a drug's efficacy for a new disease.

All clinical trials are governed by the French law known as "loi Huriet." This law protects the persons involved in biomedical research and provides a framework in which biomedical experimentations on human subjects can take place. Each of these four phases involves some form of biostatistical analysis where the core competencies of the CROs are challenged. For example, Mehta and Peters (2007) claim that the bulk of statisticians' work in conducting clinical trials is in analysing data, segmenting populations, and developing specific sets of human subjects for trials. Bhattacharya (2004) claims that, given the skill base, bio-informatics and bio-informatics software development are areas where India is creating a niche for itself with notable success. In such circumstances, we claim that the value-added over time may result in the MPCs becoming dependent on services provided by CROs in developing countries.

4. Managing core competency in networks

With the growing complexity of process development, R&D firms like Pfizer have come to realize that they need to collaborate with other organizations that have expertise (Mehta & Peters, 2007). In outsourcing core activities, MPCs must manage their relationships with CROs. Managers face many challenges as they bring new products to market (McDermott & Coates, 2007). McDermott and Coates (2007) claim that these managers are faced with an array of external sourcing options. Although outsourcing decreases risk for the MPCs, it also allows other firms (e.g. CROs) to develop critical expertise and competencies. As such, there is an increasing need for strategies that help MPCs to build new core competencies such as managing the relationship between alliances (McDermott & Coates, 2007), managing employee relations within alliances (Quinn, 1999), and practicing a balanced approach when outsourcing non-core activities (Rothaermel, Hitt & Jobe, 2006). Empirical evidence from the microcomputer industry provides broad support for balancing activities within firms and network partners (Rothaermel et al., 2006). While this body of

research provides a good foundation, the authors suggest that future research should examine other industries over time (Rothaermel et al., 2006).

While new core competencies are being developed in MPCs, CROs also need to build and enhance new core competencies. Maintaining the right balance between outsourcing and competence building can prove challenging for managers in dynamic industries (Brown & Eisenhardt, 1995). For example, to manage a balance, MPC managers typically remove operational layers and process overlaps by accessing appropriate skills and knowledge. CROs need to fill the void by developing new competencies. These competencies could include the development of bio-statistical process, data mining, and accreditation with governing bodies. In such cases the service providers can leverage their new found competencies to sharpen their competitive edge while the MPCs, whose core competency may have shifted away from research and development to relationship management, are disadvantaged competitively. Furthermore, by streamlining the network operational responsibilities the outsourced operators may build resources that can support forward-looking corporate strategies of suppliers better than the suppliers who use their own resources to support their future operations. For example, MPCs can streamline network operations with the help of outsourced operators such as CROs and focus on developing drugs. From the perspective of the CROs, however, the challenge will be to add value to the suppliers by expediting the drug development process (Lerner, 1997). CROs may also have differential skills and knowledge, complementary assets, management systems and routines that provide the bases for capabilities, and the flexibility to sustain competitive advantage (Teece, Pisano, & Shuen, 1990). MPCs need to understand the operations of CROs in conducting clinical trials processes rather than, attempt to manage their internal process activities.

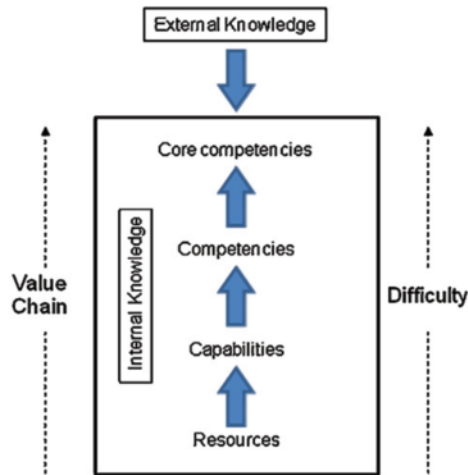
P2. MPCs need to understand how CROs perform their own internal processes and activities rather than the attempt to manage these operations for them.

Comment: This proposition claims that MPCs ought to understand the workings of the CROs in the country (e.g. India) and how CROs can facilitate the production process by using their core competencies, such as publishing reports that adhere to the requirements of drug administrators (e.g. FDA), the skills requirements, collective learning, and exchange of information.

Case illustration: To link strategies, MPCs need to have centralized resources to manage outsourcing. "The business of outsourcing is too complex [and it needs to be managed]" says Karl Clauss of Clauss and Associates, a New York based business consulting group (Moran, 1997). Outsourcing can expedite the drug development process in the face of increasing time-to-market pressures (Wong et al., 2006). Dr Vasella (CEO, Novartis) believes that MPCs need to look outside because "we can't do it all ourselves" (*The Economist*, January 27, 2007). MPCs need to make sure that the CROs are, for example, FDA accredited. The business literature suggests that, in such instances, practitioners must give CROs a well-defined set of needs and a detailed set of criteria that they must follow (Lerner, 1997). From the perspective of the CROs, regular contact with the MPCs could establish and enhance the relationship and validate the process requirements, thereby sharing the risk (Lerner, 1997). MPCs ought to establish whether the CROs have had previous off-shore experience, have advanced security and control, have the capacity to share risk, and have the necessary infrastructure and human resource skills (Larson, 1992; Wong et al., 2006).

5. Core competency and knowledge is cumulative in sustaining competitive advantage

Prahalad and Hamel (1990) contend that "core competencies are the collective learning in the organizations, especially how to coordinate diverse production skills and integrate multiple streams of



Source: Adapted from, Javidan, M (1998) Core competence: What does it mean in practice? *Long Range Planning*, 31(1) p. 62

Fig. 2. Breakdown of the main components of core competence thinking.

technologies.” They argue that core competence is communication, involvement, and a deep commitment to working across organizational boundaries. However, as firms move away from vertical integration, industrial restructuring has given rise to outsourcing of activities (Achrol, 1997).

Understanding how communication, involvement, and deep commitment work across organizational boundaries over time is important. Prahalad and Hamel (1990) claim that collective learning and sharing knowledge constitute core competencies that must unite around individuals within firms. However, their research does not address how core competencies can benefit networked firms or individuals in the network in order to recognize opportunities for blending their functional expertise with those of others in new, interesting ways. With organizations becoming horizontally integrated, individuals within the firm need to recognize opportunities for sharing knowledge with others in the network to develop new opportunities.

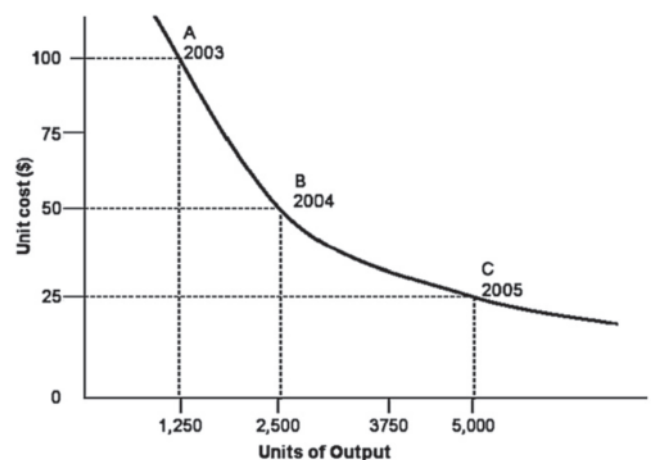
The concept of core competence has been developed to support more efficient identification and utilization of an organization's strength. The assumption is that core competencies change more slowly over time than products and markets, and are cumulative. Javidan (1998) has criticized the relatively loose application of the core competency concept. Javidan (1998) argues that to make core competence concepts more specific, resources – physical, human and organizational – should be used as inputs directed at the firm's value chain, as shown in Fig. 2 below.

Resources alone are frequently not enough to generate competitiveness over other firms. In creating a competitive advantage, a firm needs the ability to make good use of resources – defined as the capability to handle a given matter – and, as the ability grows over time, to utilize the available resources to create new resources, such as skills (through new technology or software application), or to open new doors to the development of new types of drugs (Javidan, 1998). In addition to this definition, we include the CRO's capacity to gain accreditation from the recognized authorities.

According to Durand (1998), competence can be connected to (a) the firm's resources and property and (b) the capabilities of individuals and organizations, knowledge, processes, routines, and culture. In organizations, competencies are sets of abilities and know how (Javidan, 1998) accumulated over time. In this paper, we define competence as accumulated knowledge gained over time and the ability of the firm to apply this knowledge in order to gain competitive advantage over other firms. Specifically, we claim that a firm's core competency is represented by its accumulated knowledge base realized through the effective use of internal and external partner-

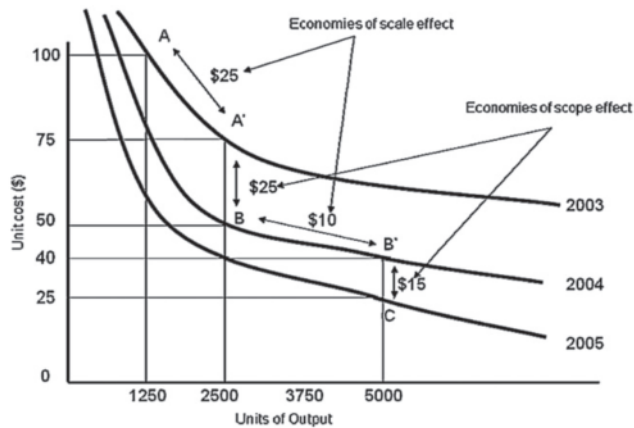
ships. Kandampully (2002) argues that the continuously updated “amorphous knowledge resource” results from the network partners that represent the firm's core competency.

Prior research into marketing strategy informs new avenues of research. These new avenues include, for example, understanding and explaining firm behavior in the realm of deployment of resources for competitive advantage (Varadarajan & Jayachandran, 1999), and a deeper understanding of the processes that impact on relationships in dynamic markets (Narayandas & Rangan, 2004). While these scholars are directing research into marketing strategy others have been building on specific areas such as knowledge-based services shared between networked participants (Quinn, 1999). Quinn (1999) argues that core competency with outsourcing strategies enables firms to focus and flatten their organizations by concentrating their limited resources and to develop world's best-practice by forming alliances with capable suppliers. For example, buyers can expand their own knowledge by sharing suppliers' experiences. Some pharmaceutical firms (buyers of services) have found that 30 percent of their research funds invested externally may produce 90 percent of their innovative leads (Quinn, 1999). In order to sustain competitive advantage it seems that organizations need to share knowledge and build on it. Companies are responsible for their own downfall by *not* sharing knowledge that provides a continuous learning environment, broadens innovators' horizons, and provides a flexible platform to innovate (Miller, 1992). Empirical studies strongly support knowledge-sharing between services providers and services receivers (Lee, 2001). Lee (2001) claims that explicit knowledge-sharing appears to be a more effective way for outsourcing success rather than implicit knowledge-sharing, because explicit knowledge is easier to understand and share with other organizations in the network. Lee's (2001) research also supports the importance of organizational capabilities in knowledge-sharing through outsourcing, building strong relationships based on trust, and commitment. Business outsourcing must share risk (Lee, 2001). However, Lee's (2001) research falls short of explaining how the service provider benefits over time as the diffusion of information permeates through the service provider organization. For example, if the service provider (i.e. the knowledge process outsourcing firm), shares knowledge with each of its clients over time, it can build and leverage that knowledge to gain entry into other markets. This accumulation of knowledge becomes the core competence of the CRO firm. For example, Davis and Devinney (1997) state that firms can gain not only economies of scale but also economies of scope through the use of accumulated experience. Davis and Devinney (1997) argue that, from an experience perspective, the advantage gained from sharing



Adapted from: Davis and Devinney (1977) *The Essence of Corporate Strategy: Theory for Modern Decision Making*, Allen & Unwin, Sydney p.85-86.

Fig. 3. Cost movement over time.



Source: Adapted from – Davis, J., Devinney, T. (1997) *The Essence of Corporate Strategy: Theory for Modern Decision Making*, Allen & Unwin, Sydney. P 85-86

Fig. 4. Scale and scope effects of cost movement over time.

knowledge and the accumulation of knowledge is difficult for rivals to imitate and can only be mimicked at a very high cost. The concept of economies of scale and scope is depicted in Figs. 3 and 4. Fig. 3 shows the unit cost of production for a firm over three years (2003–2005). The figure shows that the output rose from 1250 units to 5000 and its unit cost fell from \$100 per unit to \$25 per unit. However, the cost gain of \$75 is misleading as it is not due to cumulative experience. Rather, according to Davis and Devinney (1997), this is due to economies of scale.

In Fig. 4, A, B and C are three separate unit cost curves, all of which depict economies of scale over three years, 2003 to 2005. This helps to separate the observed cost changes into those due to scale efficiency and those due to experience gained by knowledge-sharing. From 2003 to 2004 the \$50 cost gain is split 50:50 or \$25 each between the effect of larger scale (A to A') and the effect of greater experience (A' to B). The 2003 to 2004 cost gain of \$25 is a \$10 scale cost gain (B to B') and a \$15 experience through knowledge-sharing gains (B' to C).

These economies of scale and scope may be transferable to other products and services, providing the firm with ever-growing sustainable competitive advantage. For example, as the predicted growth (i.e. growing number of CROs in developing countries like India) and the competition between the CRO industry places downward pressure on costs, MPCs will have little choice but to transfer clinical trial activities to free-up costs for development of new drugs (e.g. "The Billion Dollar Pill" – *The Economist*, January 27, 2007, p61). In such circumstances, CROs will benefit from economies of scale and scope. The accumulative benefits gained by CROs in knowledge and sharing this knowledge with MPCs will provide a win-win situation for both parties. MPCs will be able to devolve their core competencies and gain by attracting skilled staff to focus on drug development. CROs will gain by attracting MPCs and demonstrating their ability to compete on price, to advise MPCs on better process activities and outcomes, and to enhance trust and commitment in the relationship.

Over time, the economies of scale and scope benefit CROs rather than the MPCs as CROs will be more attuned to changes in regulations (e.g. FDA) and market expectations; CROs will enjoy sustainable competitive advantage thereby attracting future MPCs; over time, core competencies in economies of scale and scope will shift from MPCs to CROs rather than from CROs to MPCs in the network. Propositions can be stated as follows:

P_{3a}. Over time, economies of scale and scope benefit CROs rather than MPCs.

P_{3b}. Over time, CROs are able to sustain competitive advantages for MPC partners.

P_{3c}. Over time, core competencies in economies of scale and scope shift from MPCs to CROs rather than from CROs to MPCs in the network.

Comment: The above propositions are interrelated. These propositions are based on the assumption that core competencies and knowledge are cumulative. Therefore, over time, a CRO may have knowledge which is considered unique to the MPC that it services in the network. This may lead to a shift of core competencies from the MPCs who are the innovators but who are dependent on the CROs to bring the innovation (drug development) to the commercialization stage.

Case illustration: In the pharmaceutical industry, independent biotechnology research organizations add 100 Gb/day to the databases of GenBank alone. No single pharmaceutical firm can hope to analyze data or match the sum of all innovation of external enterprises in its value chain ... Innovative companies focus on certain activities and outsource not only product distribution but also basic research, combinatory chemistry, clinical trials, and field monitoring ... By specializing, many suppliers [CROs] have developed in-depth knowledge, skill, investment, infrastructures, and innovative capabilities for their segment of the value chain [over time] ... [These competitive] advantages are well beyond those that any integrated expertise could obtain (Quinn, 2000). Specialists [like CROs] can develop greater knowledge depth [economies of scope], invest more ... be more efficient [economies of scale] ... attract highly trained people... be more innovative ... than their [network] counterparts (Quinn, 1999).

6. Learning in networks

Learning is an integral part of the core competency of a firm. Prahalad and Hamel (1990) describe how core competencies require coordination and integration of activities which can be achieved through collective learning. We consider collective learning is dynamic and can be enriched over time through appropriate training programs to skilled employees and through the diffusion of industry information within a firm and, more so, within networks.

The concept of collective learning is not new. Rogers (1995) claims that a social system is a kind of collective learning in which the experiences of early adopters of an innovation, transmitted through interpersonal networks, determine the rate of adoption. Rogers (1995) cites a number of clinical trials and drug testing research and discusses the way in which impact of the trials in networks could be both a success and a failure depending upon how information was communicated through the social network system. Prior research on partnering suggests that collaboration enhances learning between partners (Hamel, 1991) and provides a strategic advantage (Teecce, 1986). Alternatively, learning may be a social construction process (Brown & Duguid, 1991). Under this view what is learned links profoundly to the conditions under which it is learnt (Powell et al., 1996). For example, CROs can conduct intensive training programs for skilled employees who can then communicate the information down the line and apply the training to work already in hand or future work. Knowledge creation occurs in the context of a community, one that is fluid and evolving rather than tightly bound or static. Powell and Brantley's (1992) research into the biotechnology industry suggests that the locus of innovation is found in a network of organizational relationships. For the network partners to be effective in a dynamic and competitive marketplace, firms need to be flexible and adapt to changes which can only occur through constant learning and application, that is, by doing. Empirical research shows that firms high on the learning curve will have a strong incentive to exclude new competitors, while firms that are learning more slowly will have weaker incentives to hinder new competitors and may even wish to encourage the entry of new firms (Hollis, 2002).

A few multinationals dominate the biotechnology sector (e.g. Pfizer, Merck, and Ranbaxy) and a large number of small firms that

support research and development. In so doing, these small firms share knowledge while learning from their strategic partners. Bagchi-Sen (2007) states that large industrial firms (e.g. chemical and pharmaceutical) have the capacity to move an innovation based on the knowledge and learning of the small firms in the network (e.g. CROs) towards the path of commercialization, provided they get approval from FDA. These CROs form strategic partnerships with the multinationals (Bagchi-Sen, 2007). The alliance fosters relationships that range from licensing agreements to product development, manufacturing, sales, and export. In order for the relationships to evolve, partners such as CROs need to enhance their learning capabilities in order to keep abreast of the technology (including R&D), licensing requirements, and market demands. Powell et al. (1996) describe that when the knowledge base of an industry, like the pharmaceutical industry, is both complex and expanding and the sources of expertise are widely dispersed and of varying depth, the locus of innovation occurs in networks of learning rather than in individual firms.

Firms developing strategic networks have the potential to access information, resources, markets, technologies, and the combined skill base of network partners. Gulati et al. (2000) state that access to information, resources, markets, and technology in the value chain stages of production allows firms to achieve strategic objectives such as sharing risks by outsourcing some activities (Gulati et al., 2000). While scale and scope economies may be an advantage for both the manufacturer and the outsourced organization, learning and knowledge-sharing may also be advantageous for firms in networks.

The concept of the learning curve was pioneered by Andress (1954). The learning curve is defined as the relationship between cumulative production and labor costs, while the relationship between total cost and cumulative production is known as the experience curve (Lilien & Rangaswamy, 2004). Conley (1970) describes how the experience curve can be utilized in the marketing area which may impact on manufacturing operations. Conley's (1970) research assumes that the manufacturer who has produced the most units probably has the lowest unit cost due to learning. However, research implies that learning as an integral component of core competency is gained when the lowest unit cost is achieved (Yelle, 1979) and market dominance becomes a competitive weapon using price as the marketing variable. The simplest form of the learning curve or experience curve is a log-linear model:

$$C_q = C_n \left(\frac{q}{n}\right)^{-b}$$

Where:

q	cumulative production to date;
n	cumulative production at a particular, earlier time;
C_n	cost of n th unit (in constant \$);
C_q	cost of q th unit (in constant \$);
b	learning constant

In practice, learning curve is expressed as a percentage:

$$r = 2^{-b} * 100$$

Where:

r	learning rate
b	learning constant

Source: Lilien and Rangaswamy (2004).

The model includes the rate of learning over time between network partners where the rate of learning between the partners is monitored in order to establish which alliance partner provides the most benefit

to the manufacturing organization. For example, both MPCs and CROs find monitoring the learning rate over time is important for identifying which CROs are performing and which are not.

For CROs to benefit they must keep abreast of market dynamics. They must be flexible and have a continuous learning culture in order to be competitive in the market place. Learning in social networks is cumulative. That is, it is fluid and evolving, or competence enhancing rather than competence destroying (Davis & Devinney, 1997). Propositions include the following:

P4. *In order to be competitive in networks, CROs need to conduct continuous training, to be flexible, and to apply knowledge over time (increase learning rate).*

P5. *In the CRO environment, learning is based on competence enhancing (i.e. incremental) processes rather than competence destroying processes, as in the case of MPCs.*

P6. *Through cumulative learning and increasing the learning rate, CROs may gain a competitive advantage over similar firms by developing unique clinical trial processes rather than by contributing to competence destroying innovations.*

Comment: The above propositions build from cumulative learning by a CRO firm with the flexibility to address market demands. For example, a drug protocol (i.e. the research framework initially supplied by MPCs) could be changed or CROs could change the protocol based on their knowledge in consultation with the MPC partner. Learning in the pharmaceutical industry (CROs and MPCs) is incremental based on the underlying strength of learning and knowledge-sharing between the network partners. Their underlying strength is based on organic chemistry which is in contrast to biotechnology firms which represent a competence destroying innovation based on immunology and molecular biology (Powell et al., 1996). This leads to P_6 where we claim that learning and developing knowledge over time may lead to the development of unique 'best practice' regarding clinical activities rather than contributing to any competence destroying innovation to gain competitive advantage.

Consider the following case example. Innovation in the pharmaceutical industry follows a cumulative model rather than a discrete model, where the prospects of variation and improvements of innovation are substantially bounded (Correa, 2004). According to a report of the National Institute of Health Care Management (NIHCM), the FDA approved 1035 new drug applications between 1989 and 2000. Of these, 35% were products with new active ingredients or new molecular entities (NME). The other 65% used active ingredients that were already available in a marketed product. The report claims that, over half (54%) were either incrementally modified drugs or new versions of medicines whose active ingredients were already available in an approved product. The remaining 11% contained the same active ingredients as those in identically marketed products (Hunt, 2002). The report claims that the most innovative drugs contributed little to the increase in new products and most growth came from products that did not provide significant clinical improvement, especially modified versions of older drugs. Barton (2000) states that the US Patent and Trademark Office granted over 171,000 patents (1989–2000) almost twice the number granted ten years earlier (1979–1989). This increase cannot be attributed alone to R&D productivity; rather, it is due to the flexibility of the patent system that permits protection of follow-on and other developments rather than new breakthrough innovations.

7. Discussion and future direction

This preliminary study focuses on the development of a number of propositions from a supplier firm (CRO) perspective in the dynamic pharmaceutical industry. These propositions in the article aim toward

stimulating further discussion. The propositions claim that diffusion as a process by which innovation is communicated over time (a) erode the current core competencies of MPCs by making them dependent on CROs for certain process activities while freeing up (MPC) resources to focus on new competencies, (b) require MPCs to understand how CROs perform their own internal processes and activities, (c) provide benefits to CROs through economies of scale and scope while sustaining a competitive advantage over similar firms in the developing countries, (d) require CROs to monitor the rate of learning in order to be competitive.

From a managerial perspective, the research suggests that managers of CROs need to monitor core competencies (best practice) with a view to “next practice” — a concept developed by Prahalad and Ramaswamy (2004, 2003). Prahalad and Ramaswamy (2003) report that managers are under pressure to create value in an intensely competitive environment. Traditional solutions such as cost reduction, reengineering, and process outsourcing (BPO), while critical, cannot solve the problems of margin pressure (Pralhad & Ramaswamy, 2004). The need to innovate by sharing knowledge, learning, increasing economies of scale and scope, and maintaining and enhancing core competencies, may pave the way for managers to sustain competitive advantage over similar firms in an increasingly networked environment. The rate-of-learning model provides managers with “what if” scenarios when contemplating the rate of learning within the organization and through its networked organizations such as MPCs and governance institutions.

Further, as firms within networks share knowledge more extensively, allowing greater focus on core competency, advantages accrue to firms that are providing the outsourced services. Specifically, by horizontally integrating (Achrol, 1997), MPCs may lose their core competence in process activities and gain in research activities. This potential imbalance must be managed by the outsourcing firms to avoid becoming too dependent and thus losing any previously gained competitive advantages.

Future research should address how knowledge-based outsourcing firms from different industries develop business models to gain competitive advantage. Such research could, for instance, compare product-based and service-based firms in different industries to aid generalizability.

Adopting a dynamic, network-focused, research posture justifies data collection via interviews, observations, and document analysis of executives in firms horizontal and vertical positions in supply chains — and to collect such data over several weeks, months, and sometimes, years. Such an approach complements and deepens theory of the innovator's dilemma (Christensen, 2003) of remaining singularly focused on older proven technologies and extends theory on the innovator's solution by organizing across multiple firms in networks for successful new product development. The present article is an emphatic call for recognizing and reporting on how executives in multiple firms share new knowledge for leveraging new product development successfully, and for further development of theory in this area.

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